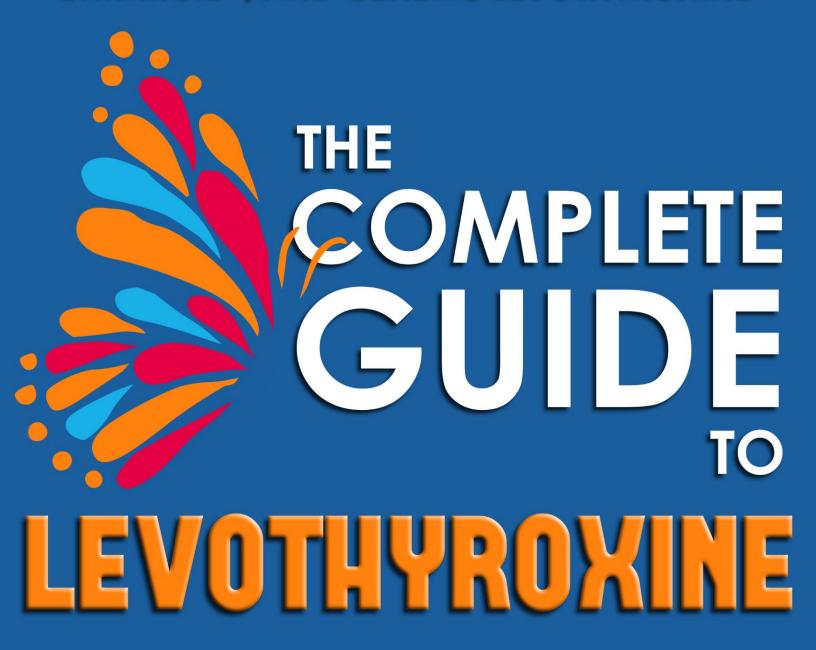
EVERYTHING YOU NEED TO KNOW ABOUT TREATING HYPOTHYROIDISM WITH LEVOXYL®, SYNTHROID®, TIROSINT®, TIROSINT®-SOL, UNITHROID®, AND GENERIC LEVOTHYROXINE



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NEW YORK TIMES BESTSELLING AUTHOR OF "LIVING WELL WITH HYPOTHYROIDISM"

Mary Shomon

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INTRODUCTION

Levothyroxine is one of the most widely prescribed drugs in the United States, and the most common medication used to treat hypothyroidism, an underactive thyroid. For most people with hypothyroidism, thyroid hormone replacement medication is lifelong. That means it's particularly important to understand this drug that is, ultimately, essential for every physical function and even survival.

In *The Complete Guide to Levothyroxine*, you'll learn about the different forms of levothyroxine, the brands and generics, and the fillers and dyes – which can all impact whether your treatment is optimal, and helps safely resolve your hypothyroidism symptoms.

And because it's usually a drug you take for life, you'll also learn about how to afford levothyroxine, or save on the cost, potentially saving up to hundreds of dollars per year on your prescription.

Finally, there are challenges in any medical treatment, and levothyroxine is no exception. So we review some of the most common issues and hurdles you may find in your treatment with levothyroxine, and most importantly, what you can do to resolve them, so that you can truly feel and live well!

This book is also accompanied by my free webinar series, the **Levothyroxine Deep Dive.** This three-part on-demand video program explains the key issues in an understandable, jargon-free way that will help fast-forward you up the learning curve. We encourage you to take advantage of this free educational program, which you'll find online at <u>mary-shomon.com/dive</u>.

Feel well and live well!

Mary Shomon

PART 1: YOUR LEVOTHYROXINE OPTIONS

LEVOTHYROXINE OVERVIEW

Levothyroxine is a synthetic version of thyroxine, the hormone – abbreviated as T4 – made and released by your thyroid gland. Levothyroxine is the active ingredient in many thyroid hormone replacement drugs that treat hypothyroidism. In hypothyroidism, your thyroid is underactive – or has been surgically removed – and can't produce enough of the thyroid hormone your body needs to function.

The Three Forms of Levothyroxine

Levothyroxine comes in three different forms:

- **Tablets** -- There are three brand name levothyroxine tablets Levoxyl[®], Synthroid[®], and Unithroid[®] in the United States. There are also many companies making generic levothyroxine tablets.
- Capsules -- There is one brand name of levothyroxine capsules Tirosint[®] and no generic capsules.
- **Oral solution** There is one brand name of levothyroxine oral solution Tirosint[®]-SOL and no generic version.

The following is the key information for each of brand as well as generic levothyroxine.





Levoxyl® Brand Levothyroxine Tablets

Description: Levoxyl[®] is a brand-name levothyroxine tablet, manufactured and distributed by Pfizer.

Form: Tablet



Drug Website: https://www.pfizer.com/products/product-detail/Levoxyl

Manufacturer/Website: Pfizer / https://www.pfizer.com

Product Information and Inquiries: 800-879-3477

https://www.pfizer.com/products/product-contact-information, Inquiries@pfizer.com

Dosage Sizes: 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg,

150 mcg, 175 mcg, 200 mcg

Drug Insert: http://labeling.pfizer.com/ShowLabeling.aspx?id=688

Excipients: Calcium sulfate dihydrate, Croscarmellose sodium, Magnesium stearate, Microcrystalline cellulose, Sodium bicarbonate

Dyes:

25 mcg: FD&C Yellow No. 6 Aluminum Lake

50 mcg: None

75 mcg: FD&C Blue No. 1 Aluminum Lake, FD&C Red No. 30 Aluminum Lake

88 mcg: FD&C Yellow No. 6 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake, FD&C

Yellow No. 10 Aluminum Lake

100 mcg: FD&C Yellow No. 6 Aluminum Lake, FD&C Yellow No. 10 Aluminum Lake

112 mcg: FD&C Yellow No. 6 Aluminum Lake, FD&C Red No. 40 Aluminum Lake, FD&C Red No. 30 Aluminum Lake

125 mcg: FD&C Red No. 40 Aluminum Lake, FD&C Yellow No. 10 Aluminum Lake

137 mcg: FD&C Blue No. 1 Aluminum Lake

150 mcg: FD&C Blue No. 1 Aluminum Lake, FD&C Red No. 30 Aluminum Lake 175 mcg: FD&C Blue No. 1 Aluminum Lake, FD&C Yellow No. 10 Aluminum Lake 200 mcg: D&C Red No. 30 Aluminum Lake, FD&C Yellow No. 10 Aluminum Lake

Typical Retail Price: \$20 - \$35

Copay Tier: 1 or 2

Average Copay: \$11 - \$33

Manufacturer Copay Card: Pfizer offers a copay card for Levoxyl[®]. The estimated savings for Levoxyl[®] under the program range from 36% to 75% of the retail cash price, and depend on such factors as the quantity purchased, and the pharmacy where it's purchased. To learn more about Pfizer's copay/savings cards to help with your copay costs for Levoxyl[®], visit the Pfizer Pathways website at https://www.pfizerrxpathways.com, or call 800-364-4767

Manufacturer Direct Purchase Program: Not available

Patient Assistance Program: The Pfizer Patient Assistance Program provides eligible patients with their Pfizer medicines for free. This program is based on income and insurance coverage. You can learn more about – and apply for – the program online at https://www.pfizerrxpathways.com/start-enrollment, or call 866-706-2400

To Report Adverse Events to Pfizer: Call 800-438-1985, or contact Pfizer at https://www.pfizer.com/contact/email

To Report Adverse Events to FDA Medwatch: Call 800-FDA-1088, or visit the FDA Medwatch website at http://www.fda.gov/medwatch



Synthroid® (levothyroxine sodium tablets, USP)

Synthroid® Brand Levothyroxine Tablets

Description: Synthroid[®] is a well-known brand-name levothyroxine tablet, and the first brand name levothyroxine drug in the U.S. market.

Form: Tablet

Drug Website: https://www.synthroid.com

Manufacturer/Website: AbbVie

https://www.abbvie.com



Product Information and Inquiries: 800-222-6885

https://www.abbvie.com/contactus.html / customerservice@abbvie.com

Dosage Sizes: 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, 300 mcg

Drug Insert: https://www.rxabbvie.com/pdf/synthroid.pdf

Excipients: Acacia, Confectioner's sugar (contains corn starch), Lactose monohydrate, Magnesium stearate, Povidone iodine, Talc

Dyes:

25 mcg: FD&C Yellow No. 6 Aluminum Lake

50 mcg: None

75 mcg: FD&C Red No. 40 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake

88 mcg: FD&C Blue No. 1 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, FD&C

Yellow No. 10 Aluminum Lake

100 mcg: D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake

112 mcg: D&C Red No. 27 & 30 Aluminum Lake

125 mcg: FD&C Yellow No. 6 Aluminum Lake, FD&C Red No. 40, Aluminum Lake,

FD&C Blue No. 1 Aluminum Lake

137 mcg: FD&C Blue No. 1 Aluminum Lake 150 mcg: FD&C Blue No. 2 Aluminum Lake

175 mcg: FD&C Blue No. 1 Aluminum Lake, FD&C Red No. 27 & 30 Aluminum Lake

200 mcg: FD&C Red No. 40 Aluminum Lake

300 mcg: D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake,

FD&C Blue No. 1 Aluminum Lake

Typical Retail Price: \$40 - \$55

Copay Tier: 2 or 3

Average Copay: \$33 - \$59

Manufacturer Copay Card: According to AbbVie, most patients with insurance pay no more than a \$25 copay for a one-month supply of Synthroid[®]. You can sign up for the Synthroid Before Breakfast Club at https://www.Synthroid.com/support/before-breakfast-club

Manufacturer Instant Coupon: For those without insurance, the club provides a \$3 off coupon for a one-month supply, and \$10 off a three-month supply. You can sign up for the Synthroid[®] Before Breakfast Club

at https://www.Synthroid.com/support/before-breakfast-club

Manufacturer Direct Purchase Program: Synthroid[®] manufacturer AbbVie offers the Synthroid[®] Direct Enrollment program, through Eagle Pharmacy. In most cases, you can get your Synthroid[®] prescription filled by mail for \$25 a month -- with or without insurance. For information on how to enroll in Synthroid[®] Direct Enrollment: https://synthroiddirectenrollment.eaglepharmacy.com

Patient Assistance Program: The Synthroid[®]/AbbVie Patient Assistance Program is based on your income eligibility, insurance coverage, and out-of-pocket medical expenses. You can review the income guidelines, and apply for the program online at https://www.abbvie.com/patients/patient-assistance/program-qualification/Synthroid-program-selection.html

To Report Adverse Events to AbbVie: 800-633-9110 https://www.abbvie.com/contactus.html / customerservice@abbvie.com

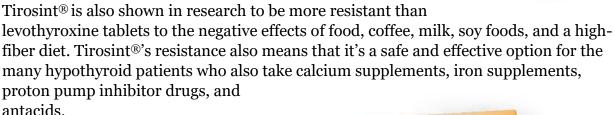
To Report Adverse Events to FDA Medwatch: Call 800-FDA-1088, or visit the FDA Medwatch website at http://www.fda.gov/medwatch



Tirosint® Brand Levothyroxine Capsules

Description: Tirosint® is a brand-name form of levothyroxine, which comes in a gelatin capsule containing a liquid form of levothyroxine. The gel caps are packaged in an individual blister pack.

Because it has no dyes, and few excipients, Tirosint[®] is considered an especially safe and effective option for people with allergies and sensitivities to dyes and excipients.



Tirosint® has also been shown to be better absorbed by hypothyroid patients who have any issues with absorption, or specific gastrointestinal or digestive conditions that negatively affect levothyroxine tablet absorption. These conditions include:

- Celiac disease
- Inflammatory bowel disease/syndrome (IBD/IBS)
- Ulcers
- Helicobacter pylori (H. pylori) infection
- Gastrointestinal reflux disease (GERD)/acid reflux
- Ulcerative colitis
- Crohn's disease
- Previous gastric bypass
- Small intestinal bacterial overgrowth (SIBO)



Form: Gelatin capsule

Drug Website: https://tirosint.com

Manufacturer/Website: IBSA Group / https://www.ibsagroup.com

US Distributor/Website: IBSA Pharma Inc. / http://www.ibsa-pharma.us

Product Information and Inquiries: 800-587-3513 https://tirosint.com/contact/medinfo@ibsapharma.com

Dosage Sizes: 13 mcg, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg,

137 mcg, 150 mcg, 175 mcg, 200 mcg

Drug Insert: https://tirosint.com/wp-content/uploads/2019/04/Tirosint-PI.pdf

Excipients: Gelatin, Glycerol, Water

Dyes: None

Typical Retail Price: \$145 - \$175 (Note: Using the manufacturer copay card, or Tirosint[®] Direct program, patient cost is no more than \$25-\$40 per month.)

Copay Tier: 3 or 4

Average Copay: \$59 - \$105

Manufacturer Copay Card: For patients with commercial health insurance and high copays, IBSA offers Tirosint[®] copay savings cards, which can be used at any retail pharmacy to save up to \$105 off your Tirosint[®] prescription every month.

According to the manufacturer, 9 out of 10 patients with insurance will pay as little as \$25 for a month's supply when using the card.

For information, go to https://Tirosint.com/patient-savings-resources/ways-to-save/copay-savings-card

To download a copay card, go to https://coupon.tirosint.com

Manufacturer Direct Purchase Program: Tirosint[®] manufacturer IBSA offers the Tirosint[®] Direct mail order program. You can pay \$50 per month, or \$120 for a three-month supply (\$40 per month) of $Tirosint^{®}$. For information on how to participate in $Tirosint^{®}$ Direct, go to tophatesize https://Tirosint.com/patient-savings-resources/Tirosint-direct-program

Patient Assistance Program: IBSA has a patient assistance program for Tirosint[®], with eligibility based on your annual household income and prescription insurance status. After you complete and return an enrollment form, if you qualify, you will automatically be mailed your first one- or three-month supply.

You will then be eligible to receive free medicine for up to one year by calling to refill your prescription every month.

You need to re-enroll each year to remain in the program. You can review the income eligibility requirements and apply for the program online at http://www.ibsapap.com

To Report Adverse Events to IBSA: 800-587-3513 / https://tirosint.com/contact medinfo@ibsapharma.com

To Report Adverse Events to FDA Medwatch: Call 800-FDA-1088, or visit the FDA Medwatch website at http://www.fda.gov/medwatch





Tirosint®-SOL Brand Levothyroxine Oral Solution

Description: Tirosint®-SOL is a brand-name levothyroxine which comes in a liquid form, packaged in an individual-dose ampule.

Because it has no dyes, and few excipients, Tirosint®-SOL is considered an especially safe and effective option for people with allergies and sensitivities to dyes and excipients.

Tirosint®-SOL is also shown in research to be more resistant than levothyroxine tablets to the negative effects of food, coffee, milk, soy foods, and a high-fiber diet. Tirosint®-SOL's resistance also means that it's a safe and effective option for the many hypothyroid patients who also take calcium



TIROSINT®-SOL 100 mcg/mL

supplements, iron supplements, proton pump inhibitor drugs, and antacids.

Tirosint®-SOL has also been shown to be better absorbed by hypothyroid patients who have any issues with absorption, or specific gastrointestinal or digestive conditions that negatively affect levothyroxine tablet absorption. These conditions include:

- Celiac disease
- Inflammatory bowel disease/syndrome (IBD/IBS)
- Ulcers
- Helicobacter pylori (H. pylori) infection
- Gastrointestinal reflux disease (GERD)/acid reflux
- Ulcerative colitis
- Crohn's disease
- Previous gastric bypass
- Small intestinal bacterial overgrowth (SIBO)

Form: Oral solution

Drug Website: https://tirosintsol.com

Manufacturer/Website: IBSA Group / https://www.ibsagroup.com

US Distributor/Website: IBSA Pharma Inc. / http://www.ibsa-pharma.us

Product Information and Inquiries: 800-587-3513 https://tirosint.com/contact/medinfo@ibsapharma.com

Dosage Sizes: 13 mcg, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg,

137 mcg, 150 mcg, 175 mcg, 200 mcg

Drug Insert: https://tirosintsol.com/wp-

content/uploads/2019/05/Tirosint SOL USPI 2018-06.pdf

Excipients: Glycerol, Water

Dyes: None

Typical Retail Price: \$145 - \$175 (Note: Using the manufacturer copay card, or Tirosint[®] Direct program, patient cost is no more than \$25-\$40 per month.)

Copay Tier: 3 or 4

Average Copay: \$59 - \$105

Manufacturer Copay Card: For patients with commercial health insurance and high copays, IBSA offers copay savings cards, which can be used at any retail pharmacy to save up to \$105 off your Tirosint[®]-SOL prescription every month. According to the manufacturer, 9 out of 10 patients with insurance will pay as little as \$25 for a month's supply when using the card.

For information, go to https://Tirosint.com/patient-savings-resources/ways-to-save/copay-savings-card

To download a copay card, go to https://coupon.tirosint.com

Manufacturer Direct Purchase Program: Tirosint[®]-SOL manufacturer IBSA offers the Tirosint[®] Direct mail order program. You can pay \$50 per month, or \$120 for a three-month supply (\$40 per month) – for Tirosint[®]-SOL. For information on how to participate in Tirosint[®] Direct, go to https://Tirosint.com/patient-savings-resources/Tirosint-direct-program

Patient Assistance Program: IBSA has a patient assistance program for Tirosint[®]-SOL, with eligibility based on your annual household income and prescription insurance status. After you complete and return an enrollment form, if you qualify, you will automatically be mailed your first one- or three-month supply.

You will then be eligible to receive free medicine for up to one year by calling to refill your prescription every month. You need to re-enroll each year to remain in the program. You can review the income eligibility requirements and apply for the program online at http://www.ibsapap.com

To Report Adverse Events to IBSA: 800-587-3513 / https://tirosint.com/contactmedinfo@ibsapharma.com

To Report Adverse Events to FDA Medwatch: Call 800-FDA-1088, or visit the FDA Medwatch website at http://www.fda.gov/medwatch





Unithroid® Brand Levothyroxine Tablets

Description: Unithroid[®] is a brand-name levothyroxine tablet, manufactured by Jerome Stevens, and distributed by Amneal. Unithroid was the first levothyroxine drug to receive new drug approval by the FDA.

Form: Tablet

Drug Website: http://www.unithroid.com

Manufacturer: Jerome Stevens https://www.jeromestevens.com

US Distributor/Website: Amneal

http://www.amneal.com

Product Information and Inquiries: 877-835-5472

DrugSafety@amneal.com

Dosage Sizes: 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200

mcg, 300 mcg

Drug Insert:

 $\underline{https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/21210lbl.pdf}$

Excipients: Acacia, Colloidal silicon dioxide, Cornstarch, Lactose, Magnesium stearate, Microcrystalline cellulose, Sodium starch glycolate

Dyes:

25 mcg: FD&C Yellow No. 6 Aluminum Lake

50 mcg: None

75 mcg: FD&C Red No. 40 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake 88 mcg: D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake,

FD&C Blue No. 1 Aluminum Lake

100 mcg: D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake

112 mcg: D&C Red No. 27 Aluminum Lake

125 mcg: FD&C Yellow No. 6 Aluminum Lake, FD&C Red No. 40 Aluminum Lake,

FD&C Blue No. 1 Aluminum Lake

150 mcg: FD&C Blue No. 2 Aluminum Lake

175 mcg: FD&C Blue No. 1 Aluminum Lake, FD&C Red No. 27 Aluminum Lake

200 mcg: FD&C Red No. 40 Aluminum Lake

300 mcg: D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake,

FD&C Blue No. 1 Aluminum Lake

Typical Retail Price: \$15 - \$20

Copay Tier: 1

Average Copay: \$11

Manufacturer Copay Card: Unithroid[®] distributor Amneal offers a copay card, and a related voucher program, which are outlined at their website at https://www.Unithroid.com/#help-patients-save. According to Amneal, with the Unithroid[®] copay card, more than 90% of commercially-insured patients pay as little as \$3 for a one-month supply. You can get a Unithroid[®] Copay Card online at https://www.activatethecard.com/7194

Manufacturer Direct Purchase Program: None available

Patient Assistance Program: None available

To Report Adverse Events to Amneal: 877-835-5472 / <u>DrugSafety@amneal.com</u>

To Report Adverse Events to FDA Medwatch: Call 800-FDA-1088, or visit the FDA Medwatch website at http://www.fda.gov/medwatch





















and other companies

Generic Levothyroxine Tablets

Description: Generic levothyroxine tablets are made and distributed by multiple manufacturers in the United States.

Form: Tablet

Manufacturers: AHP, Alvogen, Amneal, API, A-S, Bryant Ranch, Denton, Direct Rx, HJ Harkins, Humco, Lannett, Lupin, Major, Medisca, Mylan, Neolpharma, Par, PD-Rx, Proficient, Provell, Quality Care, Sandoz, and others

Dosage Sizes: 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, 300 mcg

Drug Insert: Contact your pharmacist.

Excipients: May include the following excipients. Check the drug insert, or ask the pharmacist, for details.

Acacia

Butylated hydroxyanisole (BHA)

Calcium sulfate dihydrate

Colloidal silicon dioxide

Cornstarch

Croscarmellose sodium

Crospovidone

Ethanol / Ethyl alcohol

Glycolate

Lactose / Lactose monohydrate

Magnesium stearate

Mannitol

Microcrystalline cellulose
Povidone / Povidone-Iodine
Silicon dioxide colloidal
Sodium bicarbonate
Sodium croscarmellose
Sodium lauryl sulfate
Sodium starch / Sodium starch glycolate
Sucrose
Talc

Dyes: Depend on manufacturer and dosage. Check the drug insert, or ask the pharmacist, for details. May include:

FD&C Blue No. 1 FD&C Red No. 27 FD&C Red No. 30 FD&C Red No. 40 FD&C Yellow No. 6 FD&C Yellow No. 10

Typical Retail Price: \$12 - \$20

Copay Tier: 1

Average Copay: \$11

Key Ways to Save on Generic Levothyroxine:

Walmart makes dosage sizes of generic levothyroxine from 25 mcg to 200 mcg available for \$4 for a one-month supply, and \$10 for a three-month supply as part of the nationwide Walmart \$4 Prescription Program. You'll find a list of all the drugs on their program – which includes levothyroxine – online at https://www.goodrx.com/blog/the-walmart-4-generic-prescriptions-list.

Honeybee Health is a discount wholesale mail order pharmacy, licensed in 41 states. Honeybee charges \$8 for a one-month supply, \$22 for a three-month supply, and \$44 for a six-month supply of generic levothyroxine, with free shipping. You can find Honeybee online at https://honeybeehealth.com.

To Report Adverse Events to FDA Medwatch: Call 800-FDA-1088, or visit the FDA Medwatch website at http://www.fda.gov/medwatch

HOW TO TAKE LEVOTHYROXINE

You should take levothyroxine in the morning, ideally on an empty stomach, at least 30 to 60 minutes before eating breakfast.

Experts also recommend you wait at least an hour after taking your levothyroxine before drinking coffee or milk, because both beverages can negatively affect absorption.

Levothyroxine absorption can also be affected by antacids that



include calcium, aluminum hydroxide, and magnesium, iron and calcium supplements, multivitamins that contain iron or calcium, and beverages like calcium-fortified juices. You should take levothyroxine **four hours before or after** these medications, supplements, or drinks.

Note that other dietary factors can impair levothyroxine absorption, including:

- Foods containing soy products
- Foods containing cottonseed meal
- Walnuts
- Grapefruit juice
- High-fiber foods and fiber supplements

For levothyroxine tablets and capsules, it's recommended that you take them with a glass of water.

Tablets can be safely split. You can't split levothyroxine capsules.

Tirosint[®]-SOL oral solution is packaged in individual dosage ampules. You can take the liquid levothyroxine directly in your mouth, or dilute it in water.

EXCIPIENTS AND DYES

What's in Your Levothyroxine Tablets?

The active ingredient in all levothyroxine drugs is the levothyroxine – the synthetic thyroid hormone -- itself. Like all medications, levothyroxine also includes excipients—the inactive and inert ingredients that serve as fillers and binders.

The following is a list of excipients you'll find in brand name and generic levothyroxine tablets. The darker orange color signifies the excipients most associated with sensitivity.

	TABLET BRANDS			GENERIC
TABLET EXCIPIENT	LEVOXYL	SYNTHROID	UNITHROID	(MAY INCLUDE)
Acacia				
Butylated Hydroxyanisole (BHA)				
Calcium Sulfate Dihydrate				
Colloidal Silicon Dioxide				
Cornstarch				
Croscarmellose Sodium				
Crospovidone / Povidone / Iodine				
Ethanol / Ethyl Alcohol				
Glycolate / Starch Glycolate				
Lactose / Lactose Monohydrate				
Magnesium Stearate				
Mannitol				
Microcrystalline Cellulose				
Talc				

What's in Tirosint® and Tirosint®-SOL?

Tirosint® capsules have three excipients: gelatin, glycerin, and water. Sensitivity or allergies to gelatin and glycerin are extremely rare.

Tirosint®-SOL oral solution has two excipients: glycerol and water. Sensitivity or allergies to glycerol are also extremely rare.

How Can Excipients Affect You?

Excipients can affect how well you absorb your levothyroxine. Switching from one brand name or generic levothyroxine tablet to another changes the excipients, and can affect how well you absorb your levothyroxine.

Keep in mind that excipients in your levothyroxine can change without advance notice. Changes to excipients are known to cause significant changes for patients, and in some cases, have even generated mass complaints to the Food and Drug Administration.

It's estimated that at least 15% of the population is allergic or sensitive to various excipients in medications. Some signs and symptoms of allergy/insensitivity to excipients include:

- Skin Rash
- Hives
- Itching
- Swelling
- Stomach Pain
- Diarrhea
- Bloating and Gas
- Migraine
- Severe Reaction/Anaphylaxis

Four excipients commonly found in many levothyroxine tablets are especially problematic for some patients:

- Acacia: This pollen-producing tree/shrub can trigger sensitivities in the 30% of the public that has seasonal pollen allergies and hay fever
- **Lactose:** This common ingredient in milk can trigger sensitivities in people who are lactose-intolerant, which is estimated by the National Institutes of Health at **65% of the population**.
- **Crospovidone/Povidone/Iodine:** Iodine can trigger symptoms in the estimated 3% of people who have an intolerance to this common excipient.

• **Glycolate/Starch Glycolate:** This common excipient can include wheat starch and gluten, a problem for the estimated 1% of the population with celiac disease, and up to 6% who have gluten sensitivity.

Which Dyes Are Used in Levothyroxine?

Every dosage of levothyroxine in tablet form comes in a different color due to the addition of dyes. The only exception is the 50 mcg dosage tablets, which are white, and free of dyes.

The FDA has approved various dyes for use in the manufacture of levothyroxine tablets and considers them all safe for use in medications. But are they truly safe? The British government and the European Union have already taken action to end the use of most dyes in medicines. And here in the U.S., the *International Journal of Occupational and Environmental Health* has said that testing on dyes is inadequate, and that because dyes are not essential ingredients, they should be removed. The Center for Science in the Public Interest, a consumer watchdog group, has petitioned the FDA to ban the use of dyes.

Some people have known sensitivity to the dyes found in levothyroxine tablets. Here are some details on the dyes included in levothyroxine tablets.

- **FD&C Blue No. 1 Aluminum Lake:** Can cause hypersensitivity reactions. In 2003, the FDA issued a Public Health Advisory to alert healthcare providers of toxicity associated with some uses.
- **FD&C Blue No. 2 Aluminum Lake:** The Center for Science in the Public Interest says that it is not safe for human consumption. The Environmental Working Group cites numerous studies looking at the potential toxicity.
- FD&C Red No. 27 Aluminum Lake: Classified as expected to be toxic or harmful in Canada.
- **FD&C Red No. 30 Aluminum Lake:** Classified as expected to be toxic or harmful in Canada.
- **FD&C Red No. 40 Aluminum Lake:** Can cause hypersensitivity reactions in some people.
- FD&C Yellow No. 10 Aluminum Lake: Limited evidence of any toxicity.
- **FD&C Yellow No. 6 Aluminum Lake:** Can cause hypersensitivity reactions in some people.

Note: Tirosint[®] capsules and Tirosint[®]-SOL oral solution contain no dyes.

POTENCY ISSUES

How Do Levothyroxine Potency Differences Affect Your Treatment?

Levothyroxine has what the FDA refers to as a "narrow therapeutic index." That means that even small variations in the amount of active levothyroxine can significantly affect whether it's effective for you. **The FDA**, **therefore**, **requires all levothyroxine drugs to fall within 95% to 105% of its stated potency**.

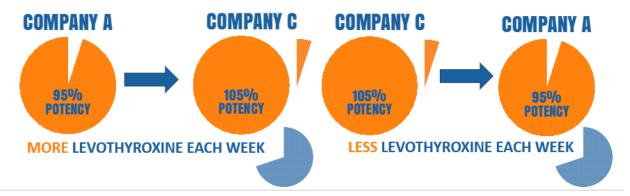
Each manufacturer -- whether brand name or generic -- tends to have the same potency rate for all the different dosages of its levothyroxine. So, for example, Company A's levothyroxine may run at 95% potency, Company B's at 100% potency, and Company C's at 105%. This information is not, however, publicly available.

These potency differences can create a challenge for your treatment. How? Let's look at an example.

Companies A and C each make a brand name or generic levothyroxine. Company A's levothyroxine is 95% potency, and Company C is 105% -- both within the FDA guidelines.

Let's say you are stable and feeling well on Company A's levothyroxine, but you must switch to Company B -- a different brand or generic. This switch may occur due to product availability, cost issues, or insurance company mandates.

When you switch from Company A to Company C's product, you get more medication – **almost ¾ of a pill more medication**, in fact, during a week of treatment. If you switch from Company C to Company A's product, you get **almost ¾ of a pill less medication** in a week. Even that difference is enough to affect your response to treatment and change your thyroid test levels.



There's another critical issue with potency: All levothyroxine drugs lose potency over time. That's why they have an expiration date. The potency of levothyroxine tablets can degrade when exposed to light, heat, and moisture. (That's a good reason NOT to store your levothyroxine tablets in the kitchen or bathroom, and instead, choose a cool, dark, dry spot!) Levothyroxine capsules – individually packaged in blister-packs -- and

levothyroxine oral solution – with doses individually packaged in ampules -- are more resistant to light, heat, and moisture compared to tablets.

The American Association of Endocrinologists (AACE), recognizing the issue of potency variations, has said:

"Thyroid disease is best managed with consistent and precise treatment with the same brand of thyroid hormone."



The best way, then, to minimize any problems from potency issues is to take the same brand of levothyroxine.

What Are the Challenges of Taking Generic Levothyroxine?

Generic levothyroxine poses an additional challenge. Every time you get a refill of levothyroxine, it can come from a different generic manufacturer.

That means that with every refill, you can get levothyroxine with potency ranging from 95% to 105% of the stated dosage.



And don't forget that every generic levothyroxine has different excipients, which may change that medication's effectiveness for you.

If you can't take a brand name, there are three ways to help minimize the impact of potency and excipient changes from refill to refill of generic levothyroxine.

1. First, if you get stabilized and feel well on a particular manufacturer's generic levothyroxine, have a discussion with your pharmacist to see if he or she can ensure that you **get refills only from that one generic manufacturer**. This can be difficult or impossible with larger pharmacy chains and mail-order

- pharmacies but may be possible if you have a relationship with a smaller, independently owned local pharmacy.
- **2.** Second, **get the largest possible quantity refill**. If you can get a three- or sixmonth supply instead of monthly refills you reduce your risk of potency variations.
- 3. Third, you can order generic levothyroxine online from the "Mail My Prescriptions" website. Mail My Prescriptions is the only site I found that lets you specify that a prescription is filled by generic levothyroxine from a specific manufacturer, in this case, Alvogen or Amneal. Mail My Prescriptions is located online at https://www.mailmyprescriptions.com

FINDING THE RIGHT LEVOTHYROXINE FOR YOU

Do You Need a Brand Name Levothyroxine?

There are some situations where a brand name drug is particularly important, because for these patients, reliable, consistent treatment is crucial, and fluctuations in potency can have serious outcomes. These include:

Pregnant women

When you're pregnant, thyroid treatment helps protect the neurological health of the developing baby, and helps prevent miscarriage, stillbirth, and premature birth

Babies born with congenital hypothyroidism and children with hypothyroidism

Babies born with congenital hypothyroidism and children with hypothyroidism who need thyroid hormone for their neurological, intellectual, and physical growth and development



Thyroid cancer survivors on "suppressive therapy"

Thyroid cancer survivors on "suppressive therapy" need consistent treatment to achieve the low or undetectable thyroid stimulating hormone (TSH) levels that help prevent thyroid cancer recurrence.

If you are on generic levothyroxine and fall into these categories, talk to your health care provider about whether a brand name levothyroxine would be a better choice.



You should also consider switching from generic to brand name levothyroxine if:

- Your thyroid test levels are not stable on generic levothyroxine
- Your thyroid test levels are optimal, but you don't feel well and continue to have symptoms on your current dosage of generic levothyroxine
- You have signs or symptoms or an allergy or sensitivity to a particular excipient and need a consistent formulation

When Should You Consider Switching from One Brand of Levothyroxine to Another?

If you are already taking a brand name levothyroxine, remember that the form, excipients, and dyes in your brand can change its effectiveness for you. Consider switching from one brand to another brand of levothyroxine when:

- Your thyroid test levels are not stable on your current brand of levothyroxine
- Your thyroid test levels are optimal, but you don't feel well and continue to have symptoms on your current brand of levothyroxine
- You have signs or symptoms or an allergy or sensitivity to excipients in your current brand of levothyroxine
- You are lactose-intolerant, and taking a brand of levothyroxine that includes lactose
- You have seasonal allergies and are taking a brand of levothyroxine that includes acacia
- You are sensitive to iodine and are taking a brand of levothyroxine that includes povidone/crospovidone
- You are sensitive to gluten and are taking a brand of levothyroxine that includes starch glycolate

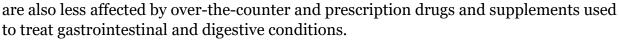


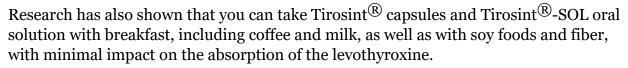
When Should You Consider Switching from Levothyroxine Tablets to Tirosint[®] Capsules or Oral Solution?

Tirosint[®] capsules were approved by the FDA in 2006 and became available in early 2007. Even though the drug has been available in the US since early 2007, many thyroid patients and physicians are not familiar with this levothyroxine treatment option. Tirosint[®]-SOL oral solution was released in the U.S. in early 2019.

Tirosint[®] and Tirosint[®]-SOL feature a liquid form of levothyroxine and are made without the common excipients found in levothyroxine tablets that can trigger allergies or sensitivities.

Research shows that if you have a gastrointestinal or digestive condition, you'll absorb levothyroxine capsules and oral solution better than tablets. Capsules and oral solution





If you are taking a generic or brand name levothyroxine tablet, you should consider switching to $Tirosint^{\textcircled{R}}$ when:

- Your thyroid test levels are not stable on a consistent dosage of your current brand of levothyroxine tablet
- Your thyroid test levels are optimal, but you don't feel well and continue to have symptoms on your current brand of levothyroxine tablet
- You have signs or symptoms of allergies or sensitivity to excipients and/or dyes in your current brand of levothyroxine tablet
- You are lactose-intolerant
- You have seasonal allergies/hay fever
- You are sensitive to iodine
- You need to eat or drink coffee or milk at the same time as you take your levothyroxine
- You eat a high-fiber diet
- You eat a diet high in soy products



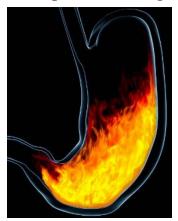
You should also consider Tirosint[®] if you take supplements or over-the-counter/prescription medications that interfere with tablet absorption. These include:

- Iron
- Calcium
- Magnesium
- Antacids that contain calcium, aluminum hydroxide and/or magnesium, such as Tums, Gaviscon, Maalox, and Mylanta
- Proton pump inhibitors like Prilosec, Prevacid, and Nexium

You should also consider switching to Tirosint[®] capsules if you have a gastrointestinal or digestive condition that is known to affect levothyroxine tablet absorption, including:

- Celiac disease
- Inflammatory bowel disease/syndrome (IBD/IBS)
- Ulcers
- Helicobacter pylori (H. pylori) infection
- Gastrointestinal reflux disease (GERD)/acid reflux
- Ulcerative colitis
- Crohn's disease
- Previous gastric bypass
- Small intestinal bacterial overgrowth (SIBO)

The Tirosint[®]-SOL oral solution is recommended for infants and children being treated with levothyroxine for hypothyroidism, and for people who can't swallow tablets or capsules.





PART 2: THE COST OF LEVOTHYROXINE

If you're a thyroid patient taking levothyroxine to treat your hypothyroidism, here's an important question: Are you paying too much?

The answer will surprise you: You may be one of the 50 percent of thyroid patients who are overpaying for this common medication that treats an underactive thyroid!

In this part of the Levothyroxine Deep Dive, we'll look at the costs of levothyroxine, and how you can stop overpaying, and even enjoy extra savings on the cost of your monthly medication! Specifically, we will look at seven ways to save on or be able to afford the cost of your levothyroxine, including:

- 1. Manufacturer Programs
- 2. Prescription Assistance Programs
- 3. Pharmacy/Grocery/Retailer Discount Programs
- 4. Outside Coupon and Discount Programs
- 5. Mail Order Pharmacies
- 6. Retail/Cash Prices
- 7. Multi-Month Refills



DRUG DISTRIBUTION AND PRICING

Before we jump into the specifics on savings, it may be helpful to review the process of how drugs – including levothyroxine – are distributed and priced, and how that affects how much you pay.

Health Plans and Pharmacy Benefit Managers

If you're insured, you pay premiums for coverage provided by your **health plan**. (Frequently, your employer is covering the cost of at least part of those premiums.)

Every health plan has what's known as a **formulary**, a list of the generic and brand name prescription drugs that are covered by the plan.

Health plans also contract with a **Pharmacy Benefit Manager**, known as a **PBM**. PBMs can be outside companies, and some plans have their own PBM divisions or spinoff companies. The PBM is a "middleman" that performs a number of functions:

- PBMs help decide which drugs go on a plan's formulary
- PBMs oversee a plan's prescription benefits
- PBMs negotiate contracts with drug manufacturers and pharmacies to maximize profits.

In exchange, the PBMs get paid by health plans for the cost of drugs dispensed, plus administrative fees.

PBMs also are frequently paid **rebates** by drug manufacturers, in exchange for being listed as a **preferred brand** on a formulary and to increase the market share for a



drug. **(**PBMs are *supposed* to give a portion of the rebate back to the health plan to help lower your costs. Unfortunately, this rarely happens.)

PRESCRIPTION DRUG PRICING

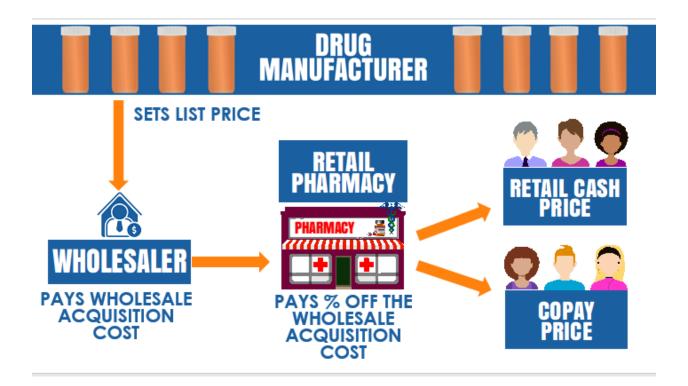
A **drug manufacturer** (pharmaceutical company) makes medications. In the case of levothyroxine, there are four brand name, and numerous generic versions of the drug. The different manufacturers of levothyroxine are covered in depth in Part 1 of the Levothyroxine Deep Dive.

The manufacturer sets a list price for every drug. They typically sell their drugs to **wholesalers** at what's called the wholesale acquisition cost, or WAC.

The wholesaler sells to **pharmacies** at a percentage off the WAC.

Pharmacies typically have two sets of prices for consumers:

- The **copayment** price called a "**copay**" for insured patients. This price is determined by your plan and the PBM.
- A **retail price** also called the "**cash price**," which is paid by someone who is uninsured, or who chooses not to use their insurance to pay for the medication.



The following is the typical retail cash price range for a one-month supply of brand name and generic levothyroxine drugs:

Levoxyl [®] Tablets	\$20 - \$35
Synthroid [®] Tablets	\$40 - \$55
Tirosint [®] Capsules	\$145 - \$175
Tirosint [®] -SOL Oral Solution	\$145 - \$175
Unithroid [®] Tablets	\$15 - \$20
Generic Tablets	\$12 - \$20



Insurance Copayments and Tiers

Your copayment is the out-of-pocket cost you are expected to pay for particular drugs. A copay can be a set amount, or a percentage of a drug's list cost, depending on your plan. Your copays are typically applied to your annual deductible. That means, you'll need to pay copays for your medications until you have satisfied the annual deductible for your plan.

Your health plan's approved formulary is divided into a number of categories – 3 or 4 is common – called **copayment tiers.** Your copay for any particular drug is based on which tier the drug is assigned to by your health plan's formulary. Tiers typically correlate to the full list price – the "sticker price" of a drug.

VCVHere's what typical formulary copayment tiers look like, and the typical tiers for generic and brand name levothyroxine:



Tier 1

Tier 1 drugs are usually generics with low list prices. They have the lowest copays and percentages. According to Kaiser Family Foundation research, the average copay for a Tier drug is \$11, or 19% of the list price.

Generic levothyroxine and Unithroid $^{\circledR}$ are Tier 1. Some plans also categorize Levoxyl $^{\circledR}$ as Tier 1.

Tier 2

Tier 2 drugs include generics with higher list prices, and some preferred brand medications. The average copay is \$33, or 26% of the list price.

Levoxyl[®] is frequently designated as Tier 2. Some plans categorize Synthroid[®] as Tier 2.

Tier 3

Tier 3 typically includes preferred and non-preferred brand name drugs with higher list prices. Your health plan may place a drug in tier 3 if there's a similar drug in a lower tier. The average copay is \$59, or 36% of the list cost.

Synthroid[®] and Tirosint[®] are frequently designated as Tier 3.

Tier 4

Some health plans also have a Tier 4, which typically includes non-preferred brands, medications with the highest list prices, and specialty drugs, prescribed for rare medical conditions. The out-of-pocket cost is highest in tier 4. The average copay is \$105, or 31% of retail cost.

While most plans designate Tirosint[®] as Tier 3, a small number of plans designate it as Tier 4.

Uncovered Drugs

Health plans sometimes choose **not** to include a brand name prescription drug on its formulary. When they do, they usually cite one of the following reasons:

- The drug has a generic version that is considered equivalent
- The drug is as equivalent to and as effective as other brands or similar drugs, but costs much more.

• The drug is considered less effective than other, similar drugs

If a drug is not on the formulary, many health plans will *not* help you pay for it. If you fill a prescription for an uncovered drug, you will need to pay the retail/cash price.

It's not common, but occasionally, I hear from thyroid patients who report that their health plan won't cover $Tirosint^{\textcircled{R}}$.

The following is a summary of the typical tier levels for brand name and generic levothyroxine drugs:

Levoxyl® Tablets:

Synthroid® Tablets:

Tier 2 or 3

Tirosint® Capsules:

Tier 3 or 4

Tirosint®-SOL Oral Solution:

Unithroid® Tablets:

Tier 1

Generic Tablets:

Tier 1



HOW MANUFACTURER PROGRAMS CAN HELP YOU SAVE

If you are taking a brand name levothyroxine drug – i.e., Synthroid $^{\mathbb{R}}$, Levoxyl $^{\mathbb{R}}$, Tirosint $^{\mathbb{R}}$ -SOL, or Unithroid $^{\mathbb{R}}$ – one of the best ways to save on the cost of your medication is to take advantage of a manufacturer savings programs.

Copay Cards and Coupons

Copay cards are special discount cards offered by drug manufacturers that provide a discount off your insurance copay. Using a copay coupon, you may be able to pay a flat rate that is less than your copay amount.

Copay cards frequently have a monthly or annual maximum amount you can save, or some can expire. There are sometimes restrictions on the maximum number of time



are sometimes restrictions on the maximum number of times you can use the card.

Copay cards are not valid for use if your coverage is under Medicare, Medicaid, the Veteran's Administration, or Department of Defense/ Tricare coverage.

Levoxyl® Copay/Savings Cards

Pfizer offers a copay card for Levoxyl[®]. The estimated savings for Levoxyl[®] under the program range from 36% to 75% of the retail cash price, and depend on such factors as the quantity purchased, and the pharmacy where it's purchased. To learn more about Pfizer's copay/savings cards to help with your copay costs for Levoxyl[®], visit the Pfizer Pathways website at https://www.pfizerrxpathways.com.

Synthroid® "Before Breakfast Club"

Synthroid[®] manufacturer AbbVie has set up the "Before Breakfast Club" to provide copay cards and a savings coupon.

- **Copay Card:** According to AbbVie, most patients with insurance pay no more than a \$25 copay for a one-month supply of Synthroid[®].
- **Instant Coupon:** For those without insurance, the club provides a \$3 off coupon for a one-month supply, and \$10 off a three-month supply.



You can sign up for the Before Breakfast Club at https://www.Synthroid.com/support/before-breakfast-club.

AbbVie offers the **Synthroid**[®] **Direct Enrollment program**, through Eagle Pharmacy. In most cases, you can get your Synthroid[®] prescription filled by mail for \$25 a month -- with or without insurance. For information on how to enroll in Synthroid[®]



Direct Enrollment: https://synthroiddirectenrollment.eaglepharmacy.com

Unithroid® Savings

Unithroid[®] distributor Amneal offers a copay card, and a related voucher program, which are outlined at their website at https://www.Unithroid.com/#help-patients-save.

- **Unithroid**[®] **Copay Card:** According to Amneal, with the Unithroid[®] copay card, more than 90% of commercially-insured patients pay as little as \$3 for a one-month supply. You can get a Unithroid[®] Copay Card online at https://www.activatethecard.com/7194
- **eVoucherRx Program:** The eVoucherRx Program does not require a card. You get your Unithroid[®] prescription filled at a participating pharmacy. According to the manufacturer, most eligible patients with commercial insurance receive an automatic co-pay reduction at participating pharmacies when picking up a Unithroid[®] prescription. You can find the list of participating pharmacies in your area online at https://evoucherrx.relayhealth.com/storelookup.

Tirosint[®] Copay Coupons and Tirosint[®] Direct Program

Tirosint[®] is a specialty form of levothyroxine that comes in both capsules, and as an oral solution.

Tirosint[®] forms of levothyroxine have very few excipients, and no dyes, and are often recommended for patients with sensitivities or allergies to ingredients and dyes in levothyroxine tablets. (You can learn more about the effect of excipients and dyes in Part 1 of the Levothyroxine Deep Dive.) When compared to levothyroxine tablets, Tirosint[®] liquid capsules and Tirosint[®]-SOL oral solution have also been shown in research to have higher resistance to food, coffee, supplements, and medications that interfere with the absorption of levothyroxine tablets. The Tirosint[®] forms of levothyroxine are also frequently recommended for people with gastrointestinal and digestive conditions that impair their absorption of levothyroxine.

Tirosint[®] capsules and solution have the highest list price and retail cash prices of all the levothyroxine drugs. The average retail cash price without any discounts or insurance is around \$175 a month, and the retail cash price with discounts/coupons is around \$145 per month.

Because it's typically categorized as Tier 3 or Tier 4, copays for Tirosint[®] average \$59 to \$105 a month.

Some health plans and Medicare Part D programs also do not cover Tirosint[®] on their formularies. The Veteran's Administration, the Department of Defense (Tricare), and Medicaid, however, cover Tirosint[®] at generally affordable copay prices.

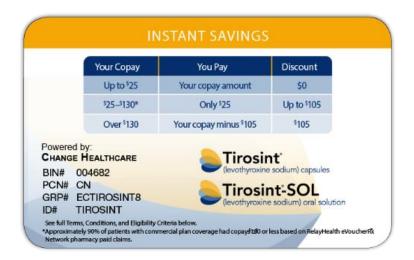
Because of the high copays and retail prices associated with $Tirosint^{\textcircled{R}}$, the manufacturer has not only a copay card, but also a special wholesale program called $Tirosint^{\textcircled{R}}$ Direct to make the drug affordable for everyone who could benefit from it.

Tirosint® Copay Cards

For patients with commercial health insurance and high copays, IBSA offers Tirosint[®] copay savings cards, which can be used at any retail pharmacy to save up to \$105 off your Tirosint[®] or Tirosint[®]-SOL prescription every month. According to the manufacturer, 9 out of 10 patients with insurance will pay as little as \$25 for a month's supply when using the card

For information, go to: https://Tirosint.com/patient-savings-resources/ways-to-save/copay-savings-card

To download a copay card, go to: https://coupon.tirosint.com



Tirosint[®] Direct

Because of the higher price of Tirosint[®], IBSA has created the Tirosint[®] Direct program. Tirosint[®] Direct is the only direct purchase program available for a brandname levothyroxine drug.

You can use the Tirosint[®] Direct Program even if you have no health insurance or prescription drug coverage, as long as you have a prescription. Under the program, you can order a one- or three-month supply of Tirosint[®] capsules or Tirosint[®]-SOL oral solution from one of IBSA's network of designated mail order pharmacies.

The designated pharmacies have specifically trained their staff on how to get you the lowest possible price. They evaluate your insurance, determine the copay, apply the Tirosint[®] copay savings card, and in most cases, if you're insured, you'll usually pay no more than \$25 a month for Tirosint[®] purchased through the program.



If you don't have insurance, or the copay is still high even with discounts – or, less commonly, your insurance doesn't cover $Tirosint^{\mathbb{R}}$ – you will have the option to pay the program's cash price of \$50 per month, or \$120 for a three-month supply (\$40 per month.)

After ordering, you'll typically receive your filled prescription by mail within three days. You'll also get a receipt that can be submitted to flexible spending account (FSA) or health savings account (HSA) administrators or health plans.

For information on how to participate in Tirosint[®] Direct, go to: https://Tirosint.com/patient-savings-resources/Tirosint-direct-program

How Can Patient Assistance Programs Help You Afford Your Levothyroxine?

Patient Assistance Programs – known as PAPs – provide free or low-cost medication for people who qualify. Your eligibility for a PAP is based on your income and health insurance status. After you apply for a PAP and provide information about your income and insurance, you'll be notified whether you are eligible.

Most major drug manufacturers have their own PAPs, and your starting place to apply is at their websites, where they provide information about their specific eligibility requirements.

Levoxyl®/Pfizer Patient Assistance Program

This program provides eligible patients with their Pfizer medicines for free. This program is based on income and insurance coverage. You can learn more about – and apply for – the program online at https://www.pfizerrxpathways.com/start-enrollment.



Synthroid[®]/AbbVie Patient Assistance Program

AbbVie's Patient Assistance Program is based on your income eligibility, insurance coverage, and out-of-pocket medical expenses. You can review the income guidelines, and apply for the program online at https://www.abbvie.com/patients/patient-assistance/program-qualification/Synthroid-program-selection.html.

Tirosint®/IBSA Patient Assistance Program

IBSA has a patient assistance program for $Tirosint^{\textcircled{R}}$ and $Tirosint^{\textcircled{R}}$ -SOL, with eligibility based on your annual household income and prescription insurance status.



After you complete and return an enrollment form, if you qualify, you will automatically be mailed your first one- or three-month supply. You will then be eligible to receive free medicine for up to one year by calling to refill your prescription every month. You need to re-enroll each year to remain in the program.

You can review the income eligibility requirements and apply for the program online at http://www.ibsapap.com.



Other PAP Programs

Beyond manufacturer programs, there are other PAPs run by non-profit organizations that may be able to help you offset the cost of medications if you are eligible. Here are several of the best places to search for patient assistance programs:

- NeedyMeds https://www.needymeds.org
- RxAssist https://www.rxassist.org/patients
- Medication Assistance Tool https://medicineassistancetool.org



RETAILER DISCOUNT PROGRAMS

Grocery stories and pharmacies like CVS, Walgreens, Rite-Aid, Kroger, Publix, Meijer, Safeway, and others have **retailer discount programs** you can join that provide discounts on medications. For example, when you're a member of these free or low-cost programs, you get discounts off the retail cash price of thousands of brand-name and generic medications.



You can search for these discount programs at NeedyMeds at https://www.needymeds.org/discount-drugs.

Also be sure to check with organizations you belong to, as some also offer pharmacy discount programs. For example, the <u>American Association of Retired People (AARP) offers a discount program</u> that saves members an average of 61% on prescriptions not covered by current insurance.

The Walmart \$4 Prescription Program

You may be aware of Walmart's nationwide \$4 Prescription Program. Some pharmacists describe the Walmart program as a "loss leader," meaning that Walmart takes a loss on some of their \$4 medications so that customers use their pharmacy for other, more profitable medications.

You'll find a list of all the drugs on their program – which includes levothyroxine – online at https://www.goodrx.com/blog/the-walmart-4-generic-prescriptions-list.

Walmart makes dosage sizes of generic levothyroxine from 25 mcg to 200 mcg available

for \$4 for a one-month supply, and \$10 for a three-month supply.

The important takeaway:

If your copay is more than \$4 for generic levothyroxine, you're overpaying!

Keep in mind that with Walmart, you won't be able to specify which generic manufacturer's product is being used to fill your prescription. You can learn why this is a problem for some thyroid



patients in Part 1 of the Levothyroxine Deep Dive program.

Costco Member Prescription Program

Costco's Member Prescription Program, available for Costco members, has Levoxyl[®] and Synthroid[®] on their preferred drug list. (You can view their full preferred drug list here.) According to Costco, as of Spring 2020, you can get a three-month supply of 88 mcg Levoxyl[®] for an estimated retail cash price of \$69.00, and a three-month supply of 100 mcg Synthroid[®] for \$125.99.

For more information, see https://www.costco.com/member-prescription-program.html.

BlinkHealth

BlinkHealth is a website that lets you preorder a prescription online at a negotiated discounted price, and then pick it up locally at one of 40,000 network pharmacies. You do not need medical insurance to use this free service. BlinkHealth is online at https://www.blinkhealth.com.

OUTSIDE COUPON AND DISCOUNT PROGRAMS

Several services offer websites where you can compare drug prices at pharmacies in your area, and find manufacturer and retailer copay cards, coupons, and discounts. The two best places to start your research include:



- GoodRx https://www.goodrx.com
- SingleCare https://www.singlecare.com

Here's an example: I used GoodRx and SingleCare to compare prices on a medication – not levothyroxine – that was not covered by my insurance. The retail cash price was around \$198 a month at most pharmacies, but SingleCare had a discount coupon for retail/cash customers that brought the cost down to \$98 at a local grocery store pharmacy. I saved \$100 *with every refill!*

Here are several other recommended sites that you can use to compare prices, and research discounts include:

- WeRx https://werx.org
- Drugs.com https://www.drugs.com
- HealthWarehouse https://www.healthwarehouse.com

I recommend that, at minimum, you search both GoodRx and SingleCare every time you fill a prescription for any drug (not just levothyroxine). Discounts can change, and some of the best coupons and savings may be available at just one of these sites.

MAIL ORDER PHARMACIES

Your health plan may offer refills of prescriptions – including levothyroxine – from their mail order pharmacy. Usually these refills are available at lower cost than at local pharmacies. It's worth contacting your health plan to find out what price difference for mail mail-order pharmacy refills.

If you are taking Unithroid[®] or generic levothyroxine you can get low prices from several wholesale mail order pharmacies. Note, however,



that these pharmacies do not accept medical insurance, so you'll pay their retail cash price.

Mail My Prescriptions

Mail My Prescriptions is a mail order pharmacy licensed in 49 states. They offer free shipping. They offer two features that are unique among the mail order pharmacies: first, they guarantee the



lowest cash-pay generic drug prices, and second, they price match any competitor. They also let you specify your preferred levothyroxine, letting you choose Amneal's Unithroid[®] or the generic levothyroxine from Alvogen.

As of Spring 2020, their price is listed as \$11 to \$22 for a one-month supply.

Mail My Prescriptions is online at: https://www.mailmyprescriptions.com.

Honeybee Health

Honeybee Health is a discount wholesale mail order pharmacy, licensed in 41 states. They offer free shipping. You won't be able to specify a generic from a particular manufacturer with Honeybee.



Honeybee charges \$8 for a one-month supply, \$22 for a three-month supply, and \$44 for a six-month supply of generic levothyroxine.

You can find Honeybee online at https://honeybeehealth.com.

Rx Outreach

Rx Outreach is unique, as it's a nonprofit charitable mail order pharmacy that provides eligible patients with access to more than 800 medications at an affordable cost.



If you're eligible, you can get generic levothyroxine for \$10 for a month's supply, \$13 for three months, \$20 for six months, and \$40 for a full year.

Rx Outreach is on the web at https://rxoutreach.org.

PAYING RETAIL/CASH PRICES

As noted, in many cases, your copay amount is *higher* than the retail cash price of levothyroxine. According to <u>a study released by the University of Southern California's</u> Schaeffer Center for Health Policy & Economics:

• 42% of patients overpay for generic levothyroxine, an average of \$6 per prescription, or \$72 a year

The overpayments for brand names are even higher!

- Around 44% of patients purchasing Synthroid[®] overpay around \$10.50 per month, or \$126 per year
- Almost 50% of all patients purchasing Levoxyl® overpaid by around \$12 per month, or \$144 per year

And we also know that many patients using Tirosint[®] overpay by as much as \$50 to \$100 per month, or \$600 - \$1200 per year!

Let's take a look at what's happening when you overpay.

Clawbacks

As mentioned, for every medication, there's your copay amount, and there's a retail cash price. Here's a question: When your copay is *more* than the cost of the drug, where do those savings go?

The answer: Frequently, those savings go back to the PBM. This is known as a **clawback.** The PBM is "clawing back" the savings between the drug's cost and your higher copay.

Here are two important things you need to know about clawbacks:

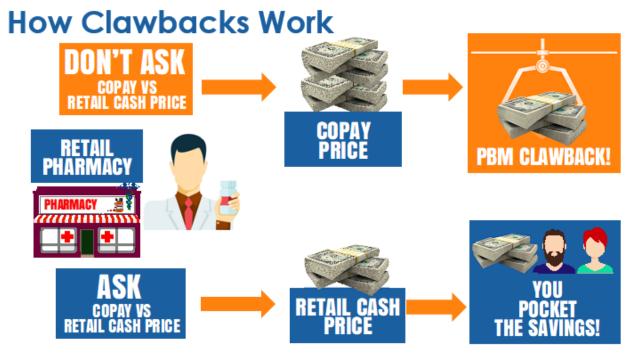
- Some states prohibit clawbacks and in those states, pharmacists are *required* to tell you if a cash price is less than your copay.
- Some states permit clawbacks, and in some of those states, gag clauses also legally *prevent* pharmacists from voluntarily telling you that you could pay less!

There's a solution to overpaying that will let YOU get the instead of a PBM:

You MUST ALWAYS ask the pharmacist directly: "Which price is lower? My copay, or the retail cash price?"

Even in states where pharmacists aren't allowed to offer this information, they *are always permitted* to tell you your lowest price option, and in fact, must do so – but *ONLY IF YOU ASK*.

So, for levothyroxine (and any drug, for that matter), ALWAYS ASK!



And remember that if you're taking a brand name levothyroxine, you'll want to have a manufacturer copay card or discount coupon on hand, so that can be factored in to your copay cost. Similarly, do your homework ahead of time to find any outside coupon and discount programs, so that you can get *every possible discount* on the retail cash price.

And don't forget that if you have a flexible spending account (FSA) or health savings account (HSA), you can use those accounts to pay for prescription medications, which may offer additional savings.

MULTI-MONTH REFILLS

Don't forget that you may be able to save by ordering more than a one-month refill for your levothyroxine. How much you save depends on whether it's a generic or brand name, and where you fill your prescription.



Here are a few examples:

- Generic levothyroxine at Walmart is \$4 a month (\$48 a year), or \$10 for a three-month supply (\$40 a year). Choosing three-month refills would save you \$8 a year.
- The retail cash price of Levoxyl[®] at CVS is \$32 a month. A 3-month supply is
- \$80. By getting 3-month refills, you'll save \$64 a year
- Annual Savings: With the Tirosint[®] Direct program, the retail cash price is \$50 a month, or \$120 for a three-month supply. Choosing three-month refills would save you \$120 a year.

SPLITTING TABLETS

Whether you split them by hand or with a pill splitter, tablet splitting is rarely precise. You can end up with uneven pieces, small pieces can become powdered, and uneven dosing. But for medications where precise dosing is not important, splitting tablets can be an effective way to cut the cost per dosage.

What about levothyroxine? Research has shown that the act of splitting a levothyroxine tablet can result in inconsistent dosing, and change the surface area of the pill, making the tablets degrade more quickly in terms of potency and stability. Because levothyroxine has a very narrow therapeutic index, splitting tablets is not generally recommended.

Note: levothyroxine in gelatin capsules can't be split under any circumstances.





SUMMARY: SAVING ON BRAND NAME AND GENERIC LEVOTHYROXINE

Here are four key takeaways:

- If you take generic levothyroxine or Unithroid $^{\mathbb{R}}$, you should not be paying more than \$4 to \$10 a month for your prescription, whether or not you have health insurance.
- If you take Levoxyl[®], you should not be paying more than around \$15-\$20 a month for your prescription if you have health insurance.
- If you take Synthroid $^{\mathbb{R}}$, you shouldn't be paying more than around \$25 a month if you have health insurance.
- If you're taking Tirosint[®] or Tirosint[®]-SOL, you should not be paying more than around \$25 a month if you have health insurance. If you're uninsured, you should not be paying more than \$40 to \$50 per month.



DRUG AND PROGRAM	COSTS OR SAVINGS	MORE INFORMATION				
LEVOXYL® TABLETS						
Levoxyl [®] Copay/Savings Cards	36% to 75% off retail cash price	https://www.pfizerrxpathways.com/start- enrollment				
Pfizer Patient Assistance Program	Free or low cost					
SYNTHROID® TABLETS						
Synthroid [®] "Before Breakfast Club" Copay Card	Usually no more than a \$25/month copay	https://www.Synthroid.com/support/before- breakfast-club				
"Before Breakfast Club" Instant Coupon (Uninsured)	\$3 off for a one-month supply \$10 off for three months					
Synthroid [®] Direct Enrollment	\$25/month	https://synthroiddirectenrollment.eaglepharmacy .com				
AbbVie Patient Assistance Program	Free or low cost	https://www.abbvie.com/patients/patient- assistance/program-qualification/Synthroid- program-selection.html				
TIROSINT® CAPSULES OR TIROSINT®-SOL ORAL SOLUTION						
Tirosint [®] Copay Savings Card	Usually no more than a \$25/month copay	https://Tirosint.com/patient-savings- resources/ways-to-save/copay-savings-card				
Tirosint [®] Direct	\$50/month, or \$120 for three months	https://Tirosint.com/patient-savings- resources/Tirosint-direct-program				
Tirosint [®] Patient Assistance Program	Free	http://www.ibsapap.com				

DRUG AND PROGRAM	COSTS OR SAVINGS	MORE INFORMATION				
UNITHROID® TABLETS Program Overview: https://www.Unithroid.com/#help-patients-save						
Copay Card	Usually no more than a \$3 copay	https://www.activatethecard.com/7194				
eVoucherRx Program	Copay reduction not specified	https://evoucherrx.relayhealth.com/storelookup				
GENERIC LEVOTHYROXINE TABLETS						
Walmart	\$4 a month, or \$10 for three months	http://www.walmart.com/pharmacy				
Honeybee	\$8 a month, \$22 for 3 months	http://www.honeybeehealth.com				

PART 3: SOLVING YOUR LEVOTHYROXINE CHALLENGES

When it comes to resolving your hypothyroidism, your medication is an important part of the picture. Your thyroid hormone replacement drug is a foundation for living and feeling well with an underactive thyroid, and this treatment is supported by healthy nutrition and a healthy lifestyle.

Here's the question EVERYONE asks:

What is the BEST thyroid drug?

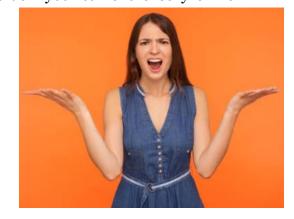
The answer?

The BEST thyroid medication for you is the one – or the particular combination – that best relieves your symptoms...SAFELY.

That leads to the next question: What should you do if your current levothyroxine

treatment *isn't* relieving your symptoms, and isn't helping you feel and live well?

That's the question we answer in this third part of the Levothyroxine Deep Dive program. In the webinar and troubleshooting guide, you can identify the key challenges you might encounter with your levothyroxine treatment, and troubleshoot the solutions that can help get you back to well-being.



SUMMARY OF CHALLENGES



The Biggest Challenges with Levothyroxine

- You are taking any form of levothyroxine -- Levoxyl $^{\mathbb{R}}$, Synthroid $^{\mathbb{R}}$, Tirosint $^{\mathbb{R}}$ -SOL, Unithroid $^{\mathbb{R}}$, or generic levothyroxine -- and you still don't feel well.
- You are taking levothyroxine and your thyroid levels keep fluctuating.

Common Challenges with Levothyroxine Tablets

- You are taking levothyroxine tablets, and you still don't feel well.
- You are taking levothyroxine tablets consistently and correctly, but your thyroid levels are not lowering, even with increasing doses of levothyroxine.
- You are taking levothyroxine tablets and you still don't feel well... and you are lactose intolerant, have seasonal allergies/hay fever, gluten sensitivity, or you're sensitive to iodine.
- You are taking levothyroxine tablets and you still don't feel well...and you also have irritable bowel syndrome (IBS), Crohn's disease, ulcers, celiac disease, or another digestive or gastrointestinal condition.
- You are taking levothyroxine tablets, including and still don't feel well...and your diet is very high in fiber.
- You are taking levothyroxine tablets and still don't feel well...and you have a high intake of soy foods and/or supplements.

Food, Supplement, and Medication Issues with Levothyroxine Tablets

- You eat breakfast, or drink coffee or milk around the same time as you take your levothyroxine tablets.
- You are taking levothyroxine tablets -- and you also take a proton pump inhibitor drug or antacid -- and you're not at optimal levels, and still don't feel well.
- You are taking levothyroxine tablets and also take calcium supplements and/or drink calcium-fortified juice -- and you're not at optimal levels and still aren't feeling well.
- You are taking levothyroxine tablets -- and you also take iron supplements or prenatal/multi-vitamins with iron -- and you're not at optimal levels and still don't feel well.

Cost and Affordability Issues with Levothyroxine

- You feel best when taking brand name Synthroid® or Tirosint®/Tirosint®-SOL, but your copay is so high that you can't afford your brand-name medication.
- You feel best on a higher-priced brand name levothyroxine like Synthroid® or Tirosint®/Tirosint®-SOL, but you are uninsured and can't afford the cost of the brand name medication.
- You are taking generic levothyroxine (or Unithroid® brand), and you are paying more than \$10 to \$15 a month for your medication.

Pharmacy Problems with Levothyroxine

- Your pharmacy is substituting generic levothyroxine tablets or lower-cost brands – for more expensive brand name levothyroxine like Synthroid, Tirosint[®], or Tirosint[®]-SOL
- Your pharmacy says they "don't have Tirosint[®]/Tirosint[®]-SOL in stock," and they try to substitute generic or brand-name levothyroxine tablets.

Nothing is Working!

• You have totally optimized every aspect of your levothyroxine treatment, and you still have hypothyroidism symptoms and don't feel well.



Are you taking levothyroxine -Levoxyl®, Synthroid®, Tirosint®, Tirosint®-SOL, Unithroid®, or generic levothyroxine -- and you still don't feel well?

CHALLENGE: You are taking any form of levothyroxine -- Levoxyl[®], Synthroid[®], Tirosint[®], Tirosint[®]-SOL, Unithroid[®], or generic levothyroxine -- and you still don't feel well.

WHAT COULD BE GOING ON?

Your thyroid levels are not at optimal levels.

ACTION PLAN:

One of the most basic challenges to effective hypothyroidism treatment is when your medication doesn't appear to be helping you achieve optimal levels of thyroid hormone.

What does "optimal" mean? Let's take a look. For thyroid hormones, there's what's known as the "normal range," or reference range. This is the broad range that's used to evaluate your test results. Some practitioners feel that all your thyroid medication needs to do is to get your levels "in the normal range" For those practitioners, where you are in the range is considered irrelevant.

But other practitioners – and many patients – know that even small changes in thyroid levels – within the normal range – can mean the difference between feeling great, and having a long list of unresolved symptoms. So, the goal is to get levels to what they refer to as the "optimal range," defined as the range where the majority of patients feel best.

Here's a quick review of the "normal" reference ranges for Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4) and Free Triiodothyronine (Free T3), and what some physicians and patients have identified as the "optimal" ranges for those tests.

Thyroid Stimulating Hormone (TSH): For TSH – a pituitary messenger hormone

used to evaluate thyroid function -the reference range varies slightly
from lab to lab. A typical reference
range is .4 to 5.5 mU/mL. Levels
below the range are evidence of
hyperthyroidism, and levels above
the range are considered evidence
of hypothyroidism.



Free Thyroxine (Free T4): Thyroxine – T4 – is an actual thyroid hormone, and

Free T4 measures the circulating thyroxine available to convert into T3 (the active thyroid hormone.) The normal reference range for Free T4 is .4 to 1.8 ng/dl. Levels below the range are considered evidence of hypothyroidism, and above the range suggests hyperthyroidism. The optimal range has been identified as the upper half of the range, or in this case, from 1.2 to 1.8.



Free Triiodothyronine (Free T3): T3 is the active thyroid hormone. A small

amount is produced by a working gland itself, and the remainder is produced as the body converts T4 into the active T3. Free T3 measures the available amount of circulating T3.

Free T3 can be confusing, because labs use three different types of measurement to report



on results. That means there are three different reference ranges.

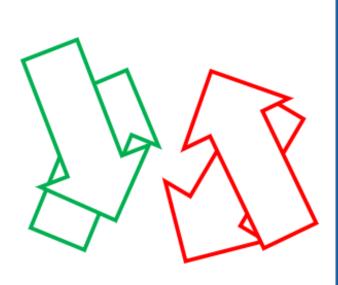
- The normal reference range for Free T3 measured in pg/dL is 260 480 pg/Dl
- The normal reference range for Free T₃ measured in pmol/L is 4 7.4 pmol/L
- The normal reference range for Free T₃ measured in pg/ML is 2.3 4.2 pg/ML

Levels below the range are considered evidence of hypothyroidism, and above the range suggests hyperthyroidism.

The optimal range has been identified as the upper half of the range. Note however that many patients who take a form of T3 as part of their treatment – as well as the prescribing practitioners – report that levels at around the 75th percentile of the range is their optimization target.

So, as a starting point, work with your health care practitioner to safely adjust your levothyroxine dosage to find out whether "normal" levels are not enough, and learn where *your* optimal levels are for wellness and the best symptom relief.





Are you taking levothyroxine, and your thyroid levels keep fluctuating?

CHALLENGE: You are taking levothyroxine, and your thyroid levels keep fluctuating.

WHAT COULD BE GOING ON?

You're not taking your levothyroxine consistently, regularly, or correctly

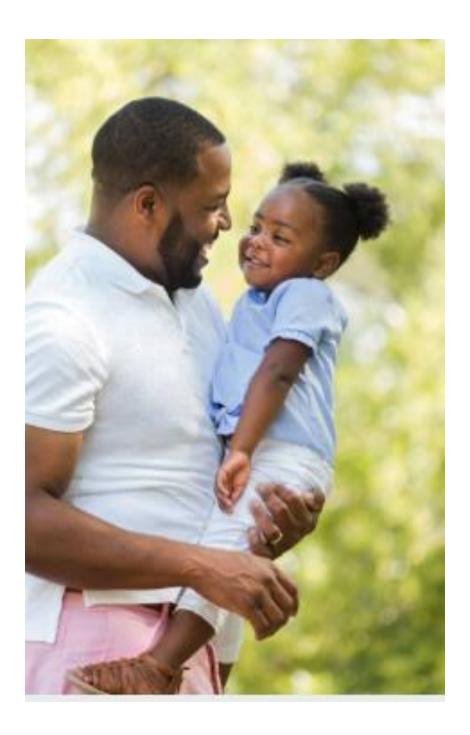
ACTION PLAN:

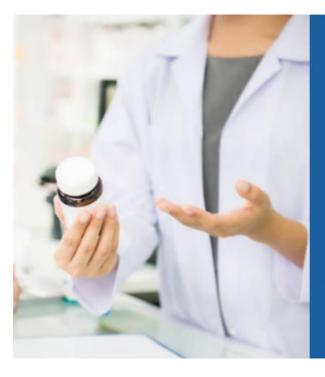
You should take levothyroxine in the morning with water, ideally on an empty stomach, at least 30 to 60 minutes before eating breakfast or drinking coffee or milk – and at least 4 hours apart from supplements that contain calcium or iron. Aim to take it at the same time, and consistently, every day.

Tablets can be safely split. You can't split $Tirosint^{\textcircled{R}}$ capsules.

Tirosint[®]-SOL oral solution is packaged in individual dosage ampules. You can take the liquid levothyroxine directly in your mouth, or dilute it in water.

Note: $Tirosint^{\textcircled{R}}$ capsules and $Tirosint^{\textcircled{R}}$ -SOL oral solution are more resistant to food, coffee, milk, and calcium and iron supplements, but experts still recommend following these guidelines for best absorption.





Are you taking
levothyroxine tablets
-- like Levoxyl®,
Synthroid®, Unithroid®,
or generic
levothyroxine -- and
you still don't feel well?

CHALLENGE: You are taking levothyroxine tablets and you still don't feel well.

WHAT COULD BE GOING ON?

If you are taking generic levothyroxine tablets, or getting different brands with each refill, you may be getting a medication with different fillers and binders with each refill. Also, each brand or generic can have a *different* potency that ranges from 95 to 105% of the stated potency. You'll do best when you are taking a consistent and precise dose of the *same* medication.

ACTION PLAN:

The easiest solution is, if you're taking a generic, to switch to a brand-name levothyroxine. If you're already on a brand, stay with that particular brand and its formulation. You'll also avoid potency fluctuations from refill to refill.

If you can't take a brand name, there are three ways to help minimize the impact of potency and excipient changes from refill to refill of generic levothyroxine.

- 1. First, if you get stabilized and feel well on a particular manufacturer's generic levothyroxine, have a discussion with your pharmacist to see if he or she can ensure that you get refills only from that one generic manufacturer. This can be difficult or impossible with larger pharmacy chains and mail-order pharmacies but may be possible if you have a relationship with a smaller, independently owned local pharmacy.
- 2. Second, get the largest possible quantity refill. If you can get a three- or sixmonth supply instead of monthly refills you reduce your risk of potency variations.
- 3. Third, you can order generic levothyroxine online from the "Mail My Prescriptions" website. Mail My Prescriptions lets you specify generic levothyroxine from Alvogen, or Amneal's Unithroid. Mail My Prescriptions is located online at https://www.mailmyprescriptions.com





Are you taking
levothyroxine tablets -Levoxyl®, Synthroid®,
Unithroid®, or generic
levothyroxine -- consistently
and correctly, but your
thyroid levels are not
lowering, even with
increasing doses?

CHALLENGE: You are taking levothyroxine tablets consistently and correctly, but your thyroid levels are not lowering, even with increasing doses.

WHAT COULD BE GOING ON?

You are probably not absorbing your levothyroxine tablets. You may be sensitive to a filler ingredient or dye. Or, you may have an undiagnosed digestive or gastrointestinal issue, or a malabsorption issue.

(Note: There are even reports of patients who were found to be properly taking levothyroxine tablets, but their thyroid tests showed no change, and doctors accused them of *secretly not taking their medication!*)

ACTION PLAN:

One option is to try a different brand levothyroxine tablet. Due to the fillers and binders added to tablets, you may have better absorption with one brand versus another.

If you aren't showing a response to levothyroxine tablets, experts recommend you switch to $Tirosint^{\textcircled{R}}$ capsules or $Tirosint^{\textcircled{R}}$ -SOL oral solution. These forms of levothyroxine were initially developed for people who can't effectively absorb tablets.





Are you taking levothyroxine tablets -- Levoxyl®,
Synthroid®, Unithroid®, or generic levothyroxine -- and you still don't feel well...and you may also be lactose intolerant, have seasonal allergies/hay fever, gluten sensitivity, or you're sensitive to iodine?

CHALLENGE: You are taking levothyroxine tablets and you still don't feel well...and you may also be lactose intolerant, have seasonal allergies/hay fever, gluten sensitivity, or you're sensitive to iodine.

WHAT COULD BE GOING ON?

You may be sensitive or allergic to the dyes or fillers and binders – known as excipients - found in most levothyroxine tablets.

Every dosage of levothyroxine in tablet form – except the 50 mcg white tablets – contains dyes, that give the tablets their color. While the dyes are FDA-approved, they have been banned by other countries, and various experts and advocates, including the Center for Science in the Public Interest, a consumer watchdog group, have



petitioned the FDA to ban the use of dyes due to potential health risks. The dyes included in levothyroxine tablets include:

- FD&C Blue No. 1 Aluminum Lake: Can cause hypersensitivity reactions. In 2003, the FDA issued a Public Health Advisory to alert healthcare providers of toxicity associated with some uses.
- FD&C Blue No. 2 Aluminum Lake: The Center for Science in the Public Interest says that it is not safe for human consumption. The Environmental Working Group cites numerous studies looking at the potential toxicity.
- FD&C Red No. 27 Aluminum Lake: Classified as expected to be toxic or harmful in Canada.
- FD&C Red No. 30 Aluminum Lake: Classified as expected to be toxic or harmful in Canada.
- FD&C Red No. 40 Aluminum Lake: Can cause hypersensitivity reactions in some people.
- FD&C Yellow No. 10 Aluminum Lake: Limited evidence of any toxicity.
- FD&C Yellow No. 6 Aluminum Lake: Can cause hypersensitivity reactions in some people.

Levothyroxine tablets also have a long list of excipients – extra ingredients beyond the levothyroxine. If you are sensitive or allergic to these filler ingredients in your levothyroxine tablets, it can interfere with the medication's effectiveness. ingredients that are most commonly associated with sensitivity, especially:

- Acacia a derivative of tree bark known to cause sensitivity and reactions in people with seasonal and pollen allergies/hay fever
- Crospovidone/Povidone which is problematic for people with iodine-sensitivity
- Lactose which can cause reactions in people with lactose intolerance

Note: some starch glycolate contains gluten, and can cause issues for some people sensitive to gluten



The following chart shows all the key excipient ingredients in tablets. The most problematic excipients are highlighted in orange. They key is to avoid any of the excipients in tablets that are problematic for you.

	TABLET BRANDS			
TABLET EXCIPIENT	LEVOXYL	SYNTHROID	UNITHROID	GENERIC (MAY INCLUDE)
Acacia				
Butylated hydroxyanisole (BHA)				
Calcium sulfate dihydrate				
Colloidal silicon dioxide				
Cornstarch				
Croscarmellose sodium				
Crospovidone / Povidone / Iodine				
Ethanol / Ethyl alcohol				
Glycolate				
Lactose / Lactose monohydrate				
Magnesium stearate				
Mannitol				
Microcrystalline cellulose				
Talc				

You can also learn more about the different excipients, and how they affect you, in Part 1 of the Levothyroxine Deep Dive.

ACTION PLAN:

If you suspect or know that you're sensitive to dyes in levothyroxine tablets, you have two options:

- 1. Switch to 50 mcg dye-free levothyroxine tablets
- 2. Switch to $\mathsf{Tirosint}^{\circledR}$ capsules or $\mathsf{Tirosint}^{\circledR}\text{-SOL}$ oral solution, which contain no dyes

If you are sensitive to excipients and other ingredients in levothyroxine tablets, you have two options:

- 1. Switch to a levothyroxine tablet that does not include the problematic ingredient(s)
- 2. Switch to Tirosint[®] or Tirosint[®]-SOL. Tirosint[®] capsules have three excipients: gelatin, glycerin, and water. Sensitivity or allergies to gelatin and glycerin are extremely rare. Tirosint[®]-SOL oral solution has two excipients: glycerol and water. Sensitivity or allergies to glycerol are also extremely rare.



Are you taking levothyroxine tablets -- Levoxyl®,
Synthroid®, Unithroid®, or generic levothyroxine -- and you still don't feel well...and you also have irritable bowel syndrome (IBS), Crohn's disease, ulcers, celiac disease, or another digestive or gastrointestinal condition?

CHALLENGE: You are taking levothyroxine tablets and you still don't feel well...and you also have irritable bowel syndrome (IBS), Crohn's disease, ulcers, celiac disease, or another digestive or gastrointestinal condition.

WHAT COULD BE GOING ON?

Your digestive or gastrointestinal condition is negatively affecting your ability to absorb your levothyroxine tablets.

ACTION PLAN:

Most doctors recommend that patients who have a digestive or gastrointestinal health condition start with or switch to Tirosint[®] or Tirosint[®]-SOL. Research has shown that the capsule and oral solution forms of levothyroxine are much better absorbed in patients who have conditions that cause absorption difficulties.



Are you taking
levothyroxine tablets
-- Levoxyl®,
Synthroid®, Unithroid®,
or generic
levothyroxine -- and
still don't feel
well...and your diet is
very high in fiber?

CHALLENGE: You're taking levothyroxine tablets, and you still don't feel well, and your diet is very high in fiber.

WHAT COULD BE GOING ON?

High-fiber foods, a high-fiber diet, and fiber supplements could be interfering with your levothyroxine absorption.

ACTION PLAN:

Make sure that you are keeping high-fiber foods and supplements 4 hours apart from your levothyroxine.

Even then, however, a high-fiber diet – which is healthy and highly recommended – can still impact your levothyroxine absorption. If you are still having issues, you may want to switch to $Tirosint^{\textcircled{R}}$ or $Tirosint^{\textcircled{R}}$ -SOL, which are more resistant to the effects of dietary fiber.



Are you taking
levothyroxine tablets -Levoxyl®, Synthroid®,
Unithroid®, or generic
levothyroxine -- and still
don't feel well...and you
have a high intake of soy
foods and/or
soy supplements?

CHALLENGE: You are taking levothyroxine tablets and still don't feel well...and you have a high intake of soy foods and/or supplements.

WHAT COULD BE GOING ON?

A diet high in soy foods – or use of high-concentration soy supplements – can interfere with your ability to absorb levothyroxine tablets effectively.

ACTION PLAN:

You can cut down on your soy consumption as a key first step. Also, note that soy supplements frequently have very high concentrations of soy isoflavones which can interfere with your absorption.

If you are still having issues, you may want to switch to Tirosint[®] or Tirosint[®]-SOL, which are better absorbed, and more resistant to the negative effects of soy on levothyroxine absorption.





Do you eat breakfast, or drink coffee or milk around the same time as you take your levothyroxine tablets (Levoxyl®, Synthroid®, Unithroid®, or generic levothyroxine)?

CHALLENGE: You eat breakfast, or drink coffee or milk around the same time as you take your levothyroxine tablets.

WHAT COULD BE GOING ON?

The food, coffee or milk could be impairing absorption of your levothyroxine.

ACTION PLAN:

You have three options:

1. Change the Timing

Ideally, you should always wait 30 minutes to an hour after taking levothyroxine tablets before eating

Also, wait an hour before drinking coffee or milk.



2. Switch to Bedtime

Talk to your provider about taking your levothyroxine tablets at bedtime, instead of the morning. This frees you up to eat and drink in the morning without restrictions.

3. Switch to Capsules or Oral Solution

You can switch to Tirosint[®] or Tirosint[®]-SOL, which are resistant to interference from food, coffee and milk.





Do you take levothyroxine tablets -- Levoxyl®,
Synthroid®, Unithroid®, or generic levothyroxine -- and you also take a proton pump inhibitor drug or antacid, and you're not at optimal levels, and still don't feel well?

CHALLENGE: You are taking levothyroxine tablets -- and you also take a proton pump inhibitor drug or antacid, and you're not at optimal levels, and still don't feel well.

WHAT COULD BE GOING ON?

Proton pump inhibitors (PPIs) like Prilosec, Prevacid, and Nexium and antacids that contain calcium, aluminum hydroxide and/or magnesium -- such as Tums, Gaviscon, Maalox, and Mylanta -- can interfere with absorption of your levothyroxine tablets.

ACTION PLAN:

- If you are taking any of these medications, be sure to take them at least 4 hours apart from your levothyroxine.
- You can also switch to Tirosint[®]/Tirosint[®]-SOL, which are formulated to be resistant to the negative effects of these medications.



Are you taking
levothyroxine tablets -Levoxyl®, Synthroid®,
Unithroid®, or generic
levothyroxine -- and also
take calcium supplements
and/or drink calciumfortified juice, and you're not
at optimal levels and still
don't feel well?

CHALLENGE: You are taking levothyroxine tablets and also take calcium supplements and/or drink calcium-fortified juice, and you're not at optimal levels and still aren't feeling well.

WHAT COULD BE GOING ON?

Calcium supplements and calcium-fortified juice can interfere with the absorption of your levothyroxine tablets.

ACTION PLAN:

You should always take calcium or drink calcium-fortified juice at least 4 hours apart from levothyroxine.

If that's unavoidable, or you're still having problems, experts recommend you switch to Tirosint[®] or Tirosint[®]-SOL, which are formulated to be resistant against interference from calcium.



Are you taking
levothyroxine tablets -Levoxyl®, Synthroid®,
Unithroid®, or generic
levothyroxine -- and you
also take iron supplements
or prenatal/multi-vitamins
with iron, and you're not at
optimal levels and still
don't feel well?

CHALLENGE: You're taking levothyroxine tablets, and you also take iron supplements – or prenatal or multivitamins with iron – and you still don't feel well.

WHAT COULD BE GOING ON?

Your iron supplements could be interfering with absorption of your levothyroxine tablets.

ACTION PLAN:

You should always take any supplements with iron at least 4 hours apart from levothyroxine. (Pay attention to whether your prenatal or multi-vitamin contains iron, as some do.)

If that's unavoidable, or you're still having problems, experts recommend you switch to $\mathsf{Tirosint}^{\mathbb{R}}$ or $\mathsf{Tirosint}^{\mathbb{R}}$ -SOL, which are formulated to be resistant against interference from iron.



Do you feel best when taking brand name Synthroid® or Tirosint®/Tirosint®-SOL, but your copay is so high that you can't afford your brandname medication?

CHALLENGE: You feel best when taking brand name Synthroid[®] or Tirosint[®]/Tirosint[®]-SOL, but your copay is so high that you can't afford your brand-name medication.

WHAT COULD BE GOING ON?

You're not taking advantage of manufacturer's copay cards for these medications. Copay cards are special discount cards offered by drug manufacturers that provide a discount off your insurance copay. Using a copay coupon, you may be able to pay significantly less than your copay amount for your levothyroxine. For Synthroid[®] and Tirosint[®]/Tirosint[®]-SOL, in most cases you'll pay no more than \$25 a month.

ACTION PLAN:

Get a manufacturer copay card for your Synthroid[®], Tirosint[®], or Tirosint[®]-SOL. **Synthroid[®] "Before Breakfast Club:"** AbbVie's "Before Breakfast Club" has a copay card for Synthroid, which gets most patients with insurance a copay of no more

than \$25 copay for a one-month supply. You can sign up for the Before Breakfast Club at https://www.Synthroid.com/support/before-breakfast-club.

Tirosint[®]/**Tirosint**[®]-**SOL Copay Savings Card:** A Tirosint[®] copay savings card will save up to \$105 off your Tirosint[®] or Tirosint[®]-SOL prescription every month. According to the manufacturer, 9 out of 10 patients with insurance will pay as little as \$25 for a month's supply when using the card.

For information, go to: https://Tirosint.com/patient-savings-resources/ways-to-save/copay-savings-card.

You can download a copay card at https://coupon.tirosint.com.





Do you feel best on a higher-priced brand name levothyroxine like Synthroid® or Tirosint®/Tirosint®-SOL, but you are uninsured and can't afford the cost of the brand name medication?

CHALLENGE: You feel best on a higher-priced brand name levothyroxine like Synthroid[®] or Tirosint[®]/ Tirosint[®]-SOL, but you are uninsured and can't afford the cost of the brand name medication.

WHAT COULD BE GOING ON?

You're not taking advantage of manufacturer's direct purchase programs for these medications, which in most cases will allow you to get your medication for less than \$50/month.

ACTION PLAN:

Fill your prescriptions through a manufacturer's "direct" mail-order program.

Synthroid[®] manufacturer AbbVie offers the Synthroid[®] Direct Enrollment program, through Eagle Pharmacy. In most cases, you can get your Synthroid[®] prescription filled by mail for \$25 a month -- with or without insurance.



For information on how to enroll in Synthroid® Direct Enrollment: https://synthroiddirectenrollment.eaglepharmacy.com/

Tirosint[®] and **Tirosint**[®]-SOL manufacturer IBSA offers the Tirosint[®] Direct mail order program. You can pay \$50 per month, or \$120 for a three-month supply (\$40 per month) – for Tirosint[®] or Tirosint[®]-SOL.

For information on how to participate in Tirosint[®] Direct, go to: https://Tirosint.com/patient-savings-resources/Tirosint-direct-program









Are you taking generic levothyroxine (or Unithroid® brand), and paying more than \$10 to \$15 a month for your medication?

CHALLENGE: You are taking generic levothyroxine (or Unithroid[®] brand), and you are paying more than \$10 to \$15 a month for your medication.

WHAT COULD BE GOING ON?

You're overpaying for these inexpensive forms of levothyroxine, and should take advantage of opportunities to get your medication at a lower cost.

ACTION PLAN:

Make it a point to pay no more than around \$3 to \$8 a month for lower-cost levothyroxine.

Specifically, you can

 Get refills of generic levothyroxine at \$4 a month from Walmart stores, with or without insurance

- Fill generic levothyroxine prescriptions by mail-order from Honeybee Health for \$8 a month, without insurance. You can find Honeybee online at https://honeybeehealth.com.
- If you have insurance, distributor Amneal offers a copay card so you can get their Unithroid[®] brand levothyroxine for \$3 a month. You can get a Unithroid[®] Copay Card online at https://www.activatethecard.com/7194
- You should always plan to research and compare prices at GoodRx (https://www.goodrx.com) and SingleCare (https://www.singlecare.com).





Is your pharmacy substituting generic levothyroxine tablets – or lower-cost brands like Unithroid® or Levoxyl® -- for more expensive brand name levothyroxine like Synthroid®, Tirosint®, or Tirosint®-SOL?

CHALLENGE: Your pharmacy is substituting generic levothyroxine tablets – or lower-cost brands like Unithroid[®] or Levoxyl[®] -- for more expensive brand name levothyroxine like Synthroid[®], Tirosint[®], or Tirosint[®]-SOL.

WHAT COULD BE GOING ON?

Your doctor has not specified the brand in a way that prevents the pharmacy from substituting with generic levothyroxine.

ACTION PLAN:

Every state except Oklahoma permits a pharmacy to substitute a generic even when your doctor has written a prescription for a brand name drug. (Note: Some states even

REQUIRE it. These include Florida, Kentucky, Massachusetts, Minnesota, Mississippi, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Washington, and West Virginia.)

To get the brand name you need -- versus the generic or a cheaper brand -- you need to ask your doctor to write the prescription in a way that prohibits substitution with a

generic or lower-cost drug. That means, the doctor needs to use the required terminology for your state on your prescription.

It's typically one of the following statements:

- Brand medically necessary
- No substitution
- Substitution Not Allowed
- DAW / Dispense as Written

In addition, some prescription pads and systems provide a box or place to check off either "No substitution" or "Dispense as Written."













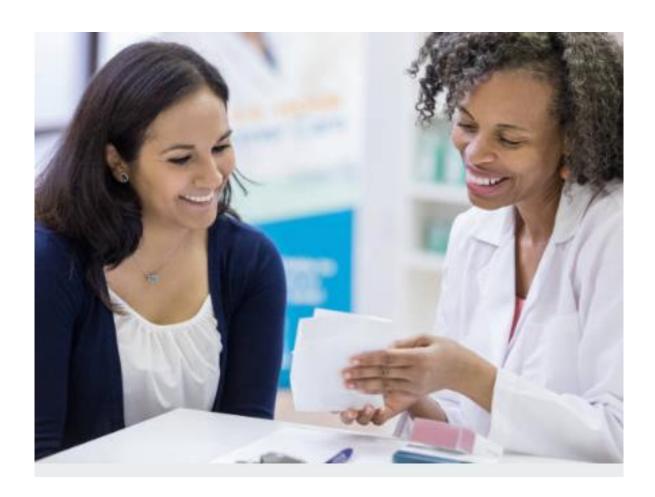
Ask your physician to write your levothyroxine prescription in a way that prevents substitution by the pharmacist in your state.

For more information, you may want to review this guide on how to prevent substitution. https://liferaftgroup.org/how-to-prevent-substitution-guide

An Important Note: It is NEVER legal for a pharmacy to substitute brand name or generic levothyroxine tablets for Tirosint[®] or Tirosint[®]-SOL. While generic and brandname levothyroxine tablets are all rated by the FDA as AB equivalent to each other, tablet forms of levothyroxine are NOT rated by the FDA as AB equivalent to Tirosint[®] capsules or Tirosint[®]-SOL oral solution.

So, legally, a pharmacist can't substitute tablets for any form of Tirosint[®]. (That doesn't always stop them from still trying, however!)

Also, be aware that if your insurance company refuses to cover a medically-necessary brand name drug, you should file a complaint with the company to review the decision.





Does your pharmacy say they "don't have Tirosint® capsules or Tirosint®-SOL oral solution in stock," and try to substitute generic or brand-name levothyroxine tablets?

CHALLENGE: Your pharmacy says they "don't have Tirosint® or Tirosint®-SOL in stock," and they try to substitute generic or brand-name levothyroxine tablets.

WHAT COULD BE GOING ON?

Levothyroxine tablets are not AB rated as equivalent to Tirosint[®] or Tirosint[®]-SOL, so technically, your pharmacist can't make that substitution without a new prescription from the doctor.

They may try anyway, however, because some pharmacies get profitable rebates from other brand-name levothyroxine drugs.

ACTION PLAN:

You can raise the issue of the AB equivalence with your pharmacy, and insist that they order the medication and fill the prescription as written.

An alternative is to fill your prescription via mail order with the Tirosint[®] Direct program. The program's designated mail-order pharmacies have trained their staff on how to get you the lowest possible price.

They evaluate your insurance, determine the copay, apply the Tirosint[®] copay savings card, and in most cases, if you're insured, you'll usually pay no more than \$25 a month

for Tirosint[®] purchased through the program.

If you don't have insurance, or the copay is still high even with discounts – or, less commonly, your insurance doesn't cover Tirosint[®] -- you will have the option to pay the program's cash price of \$50 per month, or \$120 for a three-month supply (\$40 per month.)



For information on how to participate in Tirosint[®] Direct, go to: https://Tirosint.com/patient-savings-resources/Tirosint-direct-program





Have you totally optimized every aspect of your levothyroxine treatment, and still have hypothyroidism symptoms and don't feel well?

CHALLENGE: You have totally optimized every aspect of your levothyroxine treatment, and you still have hypothyroidism symptoms and don't feel well.

WHAT COULD BE GOING ON?

What if you have optimized your levothyroxine treatment in every way, and you're still not feeling well? For some patients -- whether due to genetics or other factors – the best hypothyroidism treatment includes not just T4, but the addition of the T3 hormone.

This means that some patients do better adding synthetic liothyronine – i.e., Cytomel – to their treatment, or feel best taking a natural desiccated thyroid drug that includes animal forms of both T4 and T3, like Nature-Throid, WP Thyroid, or Armour.

There are also hypothyroidism patients who have underlying autoimmune disease like Hashimoto's, or additional hormonal imbalances, such as perimenopause/menopause or adrenal dysfunction.

Finally, even with fully optimized levels and medication, some hypothyroid patients continue to have symptoms because other factors are not being addressed, such as nutrition, sleep, and stress management.

ACTION PLAN:

T3

You may be one of the patients who feels better on and/or needs a combination T4/T3 treatment. Talk to your health care provider about the possibility of testing your Free Triiodothyronine (Free T3) level, and potentially adding a T3 medication to your treatment. There are several ways to do this:

- Add synthetic T3 (generic liothyronine, Cytomel) tablets to your levothyroxine treatment
- Add a natural desiccated thyroid drug (like Nature-Throid, WP Thyroid, Armour, or generic NP Thyroid) to your levothyroxine treatment
- Switch to a natural desiccated thyroid drug



Autoimmunity and Hormonal Imbalances

Work with your health care provider to evaluate and address issues regarding elevated antibodies, and unchecked autoimmunity and inflammation.

In addition, identify other unresolved hormonal imbalances, including adrenal, sex hormones, and insulin-glucose balance, and address them.





Lifestyle

If lifestyle factors -- including insufficient sleep, nutritional deficiencies and imbalances, and chronic stress are contributing to your continuing symptoms, work with your health care provider to evaluate and address these factors.



THE THYROID TUNEUP

Have you fully optimized your thyroid treatment with levothyroxine, but still struggling? Are you wondering what your next steps should be?

For comprehensive guidance on combination T4/T3 treatment, evaluating and lowering antibodies, addressing hormonal imbalances, and modifying lifestyle factors for optimum health, you may want to take the detailed three-part video webinar/ebook course – The Thyroid Tuneup – to quickly get fully up to speed.

The Thyroid Tuneup program includes three video webinars, and a detailed 100+-page Owner's Manual ebook.

The program also includes three bonus guides, and a full-length MP3 downloadable version of the popular Thyroid Meditation guided meditation audio program.

You can learn more about the Thyroid Tuneup, and sign up for this life-changing program, at https://maryshomon.podia.com/thyroid-tuneup



MARY SHOMON

Mary Shomon is an internationally-recognized writer, award-winning patient advocate, health coach, and activist, and the *New York Times* bestselling author of 15 books on health and wellness, including the *Thyroid Diet Revolution* and *Living Well With Hypothyroidism*.

On social media, Mary empowers and informs a community of more than a quarter million patients who have thyroid and hormonal health challenges.

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