

Your Guide to Treating Hypothyroidism with Natural Desiccated Thyroid



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Contents

Introduction	5
Natural Thyroid Guide Online	7
1. Thyroid Hormone: T4 and T3	8
2. About Hypothyroidism	10
3. Causes of Poor Conversion of T4 to T3	11
Thyroid Stimulating Hormone (TSH)	11
Triiodothyronine (T3) and Free T3	12
Reverse T3 (RT3)	12
4. Hypothyroidism Treatment	13
Levothyroxine	13
The Need for T3	14
Three Ways to Add T3	
1. Add synthetic T3 to levothyroxine	
2. Take custom-compounded levothyroxine/ liothyronine	
3. Take natural desiccated thyroid	16
5. About Natural Desiccated Thyroid	
The Active Pharmaceutical Ingredient (API)	
NDT Brands	19
6. Natural Desiccated Thyroid Brands	21
Armour® Thyroid (Thyroid USP) Tablets	22
Nature-Throid® (Thyroid USP) Tablets	23
WP Thyroid® (Thyroid USP) Tablets	
NP Thyroid® / Thyroid USP Tablets / Generic NDT	25
7. Compounded Natural Desiccated Thyroid	26
An Alternative to Nature-Throid® and WP Thyroid® Tablets	
8. Do You Need Natural Desiccated Thyroid?	28
9. A Timeline and History of Natural Desiccated Thyroid	30

10. Natural Desiccated Thyroid: The Current Situation	34
I Have Questions!	
The Biologics Issue	40
What Can You Do?	41
Speaking Up About NDT	42
1. Contact the FDA!	42
2. Report Adverse Effects	42
3. Flood the FDA on Social Media!	43
4. Stay Informed	43
11. Natural Desiccated Thyroid: Myths and Controversies	44
"NDT is too old fashioned"	44
"There's no difference, so you should just take levothyroxine"	45
"Levothyroxine controls thyroid levels better than NDT" and	
"Levothyroxine is more effective than NDT"	45
"NDT is not FDA-approved"	46
"NDT is not consistent!"	47
"You don't need T3!"	48
"It's dangerous! T3 levels are too high on NDT!"	49
"T3/T4 ratios are too high on NDT!"	50
"I only prescribe levothyroxine!"	50
"Levothyroxine is the only 'accepted' treatment" and	
"My medical society doesn't support the use of NDT"	51
"You'll get mad cow disease!"	51
"NDT is not a prescription drug"	52
12. Conversion Chart: Natural Desiccated Thyroid, Levothyroxine,	and
Liothyronine/T3	
13. Natural Desiccated Thyroid Prescriptions and Substitutions	54
Prescriptions	
Preventing Pharmacy Substitutions	58

14. Natural Desiccated Thyroid: Costs and Savings	59
Prices as of October 2021	
Armour® Thyroid	60
NP Thyroid® / Generic Natural Desiccated Thyroid Costs	61
Compounded NDT	61
15. Starting and Taking Natural Desiccated Thyroid	62
Some Additional Considerations About How You Take NDT	
Keeping Your Provider Informed	
Contact Your Provider When	
16. Finding Natural Desiccated Thyroid-Friendly	
Healthcare Practitioners	66
Find a Thyroid Doctor - from RLC Labs	
Recommended Doctor List - from ThyroidChange	
Hypothyroidism Telemed Clinic - Paloma Health	
Ask for Referrals	
Practitioner Databases	68
17. Order Your Own Thyroid and Other Lab Tests	69
Paloma Home Thyroid Test Kit	
Lab Tests with Ulta	
The Benefits	71
How it Works	72
Individual Tests from Ulta	73
About Mary Shomon	74
Mary Shomon's Thyroid Support Group on Facebook	
Personal Coaching with Mary Shomon	74
Books from Mary Shomon	75
Free Email Newsletter	75
The Thyroid Tuneup	76
The Levothyroxine Deep Dive Educational Program	77
The Thyroid Deep Dive Podcast	77

Introduction

Thyroid hormone replacement medications to treat hypothyroidism – an underactive thyroid – are among the most widely prescribed drugs in the United States. For most people with hypothyroidism, thyroid hormone replacement medication is lifelong. That means it's crucial to understand your treatment, which is ultimately essential for every physical function and even survival.

In the *Natural Thyroid Guide*, you'll learn about natural desiccated thyroid (NDT) drugs, including the brands – Armour® Thyroid, Nature-Throid®, WP Thyroid®, and NP Thyroid® – and compounded NDT options from specialty pharmacies.

NDT is a doctor-prescribed thyroid hormone replacement treatment – an alternative to levothyroxine drugs like Synthroid. While levothyroxine has a synthetic form of one hormone, thyroxine (T4), NDT includes natural forms of two key thyroid hormones: T4 and triiodothyronine (T3).

The *Natural Thyroid Guide* also covers the history of NDT, myths, and controversies surrounding NDT treatment, and how to safely optimize your treatment to resolve your hypothyroidism symptoms.

And because you usually take thyroid hormone replacement for life, the *Natural Thyroid Guide* also focuses on saving on the cost of your NDT.

When it comes to NDT, there are also challenges you may face – including finding a practitioner, shortages and recalls, and overcoming the misinformation on NDT that's rampant in the medical community. The *Guide* arms you with resources and information to help.

Don't forget that the *Natural Thyroid Guide* is also accompanied by my free webinar, "NDT101." This on-demand video webinar program explains all the critical issues in an understandable, jargon-free way that will help fast-forward you quickly up the learning curve. I encourage you to take

advantage of this free educational program, which you'll find online at www.naturalthyroidguide.com. You'll also find all the resources from this Guide online at the site, as well as an opportunity to sign up for a free email newsletter featuring NDT updates to help you stay informed.

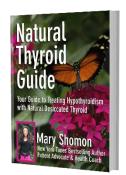
You can also join a support community on Facebook, at https://www.facebook.com/NaturalThyroidGuide, and on Instagram, follow https://www.instagram.com/naturalthyroidguide for information and updates.

Feel well and live well!

Mary Shomon

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Natural Thyroid Guide Online



This book is part of the complete Natural Thyroid Guide educational program from Mary Shomon, provided free for

thyroid patients. The Natural Thyroid Guide educational program includes:



https://www.naturalthyroidguide.com

Webinar: NDT101 – A free, one-hour, ondemand video webinar that covers everything you need to know about natural desiccated thyroid, located at https://www.naturalthyroidguide.com/webinar

Free Newsletter: You can sign up at: https://www.naturalthyroidguide.com/newsletter



https://www.facebook.com/NaturalThyroidGuide



https://www.instagram.com/naturalthyroidguide



1. Thyroid Hormone: T4 and T3

The thyroid gland's job is to make thyroid hormones. Thyroid hormones help all your organs, muscles, and glands function properly. Every part of your body needs thyroid hormone, especially your heart, brain, liver, digestion, bones, and muscles. Thyroid hormones regulate the body's metabolism and the energy required for your cells and body functions, including:

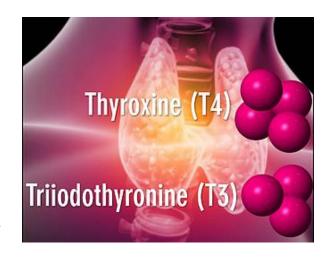
- Thinking and memory
- Neurotransmitters
- Breathing
- Metabolism
- Digestion
- Elimination
- Body weight
- Calorie burning
- Hair growth
- Healing
- Immune strength
- Fertility
- Sex drive
- Overall energy
- Muscle strength
- Muscle recovery
- Menstrual cycle
- Breastfeeding
- Mood
- Nerve function



The two most important hormones made by your thyroid are:

- Thyroxine (T4) the 4 stands for 4 atoms of iodine
- Triiodothyronine (T3) the 3 stands for 3 atoms of iodine

Every day, a healthy thyroid makes about 80 to 100 micrograms of T4 and 20 to 40 micrograms of T3. That's a ratio of about 80% T4 to 20% T3.



What happens to T4?

Some binds to proteins...and is unusable

PROTEIN

T4

Some converts into active Free T3
(after losing an iodine molecule)

T4

Free T3

The rest converts into inactive and unusable Reverse T3

Reverse T3

T4 is a STORAGE "prohormone." It goes through a conversion process before the body uses it.

Before conversion, some T4 binds to proteins and is unusable.

Some T4 loses a molecule of iodine and converts into active **Free T3**. Free T3 is the active thyroid hormone that relieves hypothyroidism, helping oxygen and energy get into cells to power ALL your body's functions.

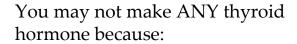
The rest of the T4 converts into an inactive and unusable form of T3, called **Reverse T3**.

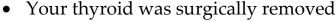
2. About Hypothyroidism

When you're hypothyroid, you don't have enough thyroid hormone. You may not make ENOUGH thyroid hormone because:

- You have autoimmune Hashimoto's thyroiditis
- You're iodine deficient
- You're taking a medication that causes hypothyroidism (i.e., lithium)

That makes you a "Low Producer."





- You had radioactive iodine (RAI) ablation treatment
- You were hypothyroid from birth

That means you're a "Non-Producer."

When you're hypothyroid, you may not have enough of the active T3 hormone because:

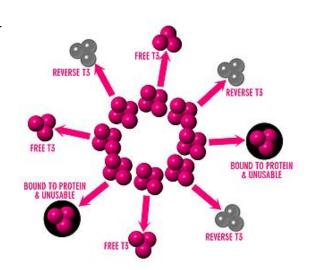
- You're not converting enough T4 into T3
- You convert T4 into too much Reverse T3

That makes you a "Poor Converter."

3. Causes of Poor Conversion of T4 to T3

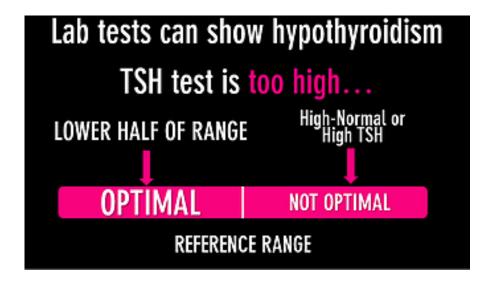
The most common causes of poor T4-to-T3 conversion include:

- Common genetic defects called polymorphisms
- Nutritional deficiencies
- Physical and emotional stress
- Surgical removal of the thyroid gland, radioactive ablation of the thyroid, and atrophy due to Hashimoto's thyroiditis



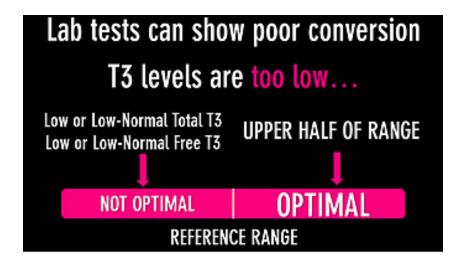
Thyroid Stimulating Hormone (TSH)

The thyroid stimulating hormone (TSH) test can give a general picture of thyroid function. Levels that are high-normal or high can indicate hypothyroidism.



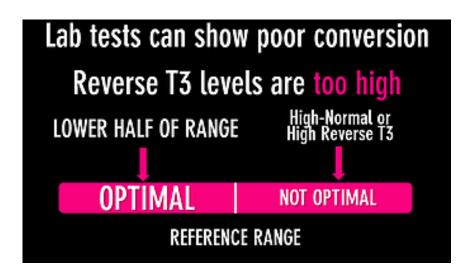
Triiodothyronine (T3) and Free T3

Total T3 and Free T3 levels that are low or low-normal can show hypothyroidism and poor conversion from T4.



Reverse T3 (RT3)

High-normal and high Reverse T3 levels can leave you with insufficient levels of the active T3 hormone.



4. Hypothyroidism Treatment

The treatment for an underactive thyroid – hypothyroidism – is thyroid hormone replacement medication. The medication puts back in the thyroid

hormone you're missing. There are three categories of manufactured thyroid hormone replacement medication:

- Levothyroxine (synthetic T4)
- Liothyronine (synthetic T3)
- Natural Desiccated Thyroid (natural T4 and T3)



Levothyroxine

The most commonly prescribed medication is levothyroxine, a synthetic form of T4 hormone introduced in the early 1950s. Since its introduction, levothyroxine has become the "preferred" treatment of endocrinologists and mainstream physicians.

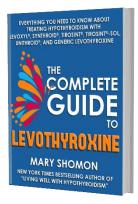
Several brands of levothyroxine tablets are available in the U.S., including Levoxyl, Synthroid, Unithroid, and Euthyrox. There are also various generic levothyroxine tablets available.

Levothyroxine is also available as Tirosint capsules and Tirosint-SOL oral solution.



For more information on levothyroxine, see the free Levothyroxine Deep Dive Program, which includes a three-part ondemand video webinar and online Guide.





You can also get the free downloadable book, "The Complete Guide to Levothyroxine," which includes everything you need to know about your levothyroxine options.

www.mary-shomon.com/dive

The Need for T3

Levothyroxine treatment assumes that:

- You produce enough T4 to convert into T3, and
- You can effectively convert T4 into T3.

But, as noted, some people are "low producers," "no producers," or "poor converters," and end up with a shortage of T3.

These patients can have continued hypothyroidism symptoms after levothyroxine treatment, with symptoms that include:

- Fatigue
- Weight Gain



- Brain Fog
- Depression
- Hair Loss
- Dry Skin
- Constipation
- Muscle Pain

The unmet need for T3 explains why some patients report much better relief of their hypothyroidism symptoms when their thyroid treatment includes T3.

Three Ways to Add T3

There are three ways you can include T3 as part of your thyroid hormone replacement treatment.

1. Add synthetic T3 to levothyroxine

Liothyronine is a synthetic of the T3 hormone. Generic liothyronine typically costs around \$15 to \$20 per month (cash price) on average. The brand name liothyronine, Cytomel, costs around \$65 to \$80 per month (cash price) on average. Keep in mind that the cost of the T3 is *in addition to* the cost of monthly levothyroxine.

2. Take custom-compounded levothyroxine/ liothyronine

Some patients get a specially compounded combination synthetic T4-T3 combination.

The quality and potency of a compounded thyroid medication vary by



compounding pharmacy, so it's vital to work with a thyroid-savvy pharmacy. Some compounding pharmacies are also very expensive, and compounded synthetic combination medication can be pricey and is usually not covered by most health insurance plans.

Note: For compounded thyroid medication, I recommend Arizona-based Foothills Pharmacy, a mail-order pharmacy that serves most of the U.S. Foothills has extensive experience in compounded thyroid hormone replacement medications.

3. Take natural desiccated thyroid

The first thyroid hormone replacement, natural desiccated thyroid (NDT), was introduced more than 50 years before levothyroxine came on the market. NDT is extracted from the dried ("desiccated") thyroid glands of pigs and has been safely used for more than a century. While levothyroxine provides only the T4 hormone, natural desiccated thyroid provides both T4 AND T3 hormones. It's usually the most affordable way to get a combination T4/T3 treatment.



5. About Natural Desiccated Thyroid









Natural desiccated thyroid (NDT) was the first treatment for hypothyroidism, introduced in the late 1800s. It was the only hypothyroidism treatment available for half a century, until levothyroxine was introduced. Since that time, it's still in use by millions of thyroid patients.

NDT is a prescription thyroid drug made from the dried ("desiccated") thyroid glands of pigs. NDT is also known as "porcine thyroid," thyroid

extract, and "desiccated thyroid extract," or DTE.

Unlike levothyroxine, which contains only the T4 hormone, natural desiccated thyroid provides both T4 and T3 hormones in a single tablet.



The Active Pharmaceutical Ingredient (API)

A drug's Active Pharmaceutical Ingredient – the API -- is the active ingredient that performs the desired action. The API in NDT drugs is Thyroid USP, a powder made from dried and processed porcine (pig) thyroid glands.

The quality and purity of the powder in Thyroid USP depend on the API's manufacturer, the regulations in the country where the API is manufactured, and the geographic source of the pigs used to produce it.

The drug manufacturer mixes the API with excipients. Excipients are the fillers, binders, coatings, and dyes that help a drug stay together as a pill or help contain and deliver the medication to your system. Unlike the API, excipients are not chemically active.

The mixture of the Thyroid USP and excipients is then formed into tablets. These tablets include standardized amounts of the two key thyroid hormones, T4 (thyroxine) and T3 (triiodothyronine). Some formulations of tablets also have an added outer coating.

Manufacturers make their NDT using APIs from different manufacturers. Specifically:

- Nature-Throid® and WP Thyroid® The API for both drugs is sourced from Specialty Process Labs (SPL) –
 https://www.splabsglobal.com –
 a US-based API manufacturer. All the animals are sourced from North America.
- Armour® Thyroid The API manufacturer is undisclosed. The geographic source of the animals is unknown.
- NP Thyroid® The API manufacturer is undisclosed. The geographic origin of the animals is unknown.

The excipients used in each brand of NDT are also unique to each brand's specifications and formulation. (See Section 6 for details on excipients by brand.)

NDT Brands

In the United States market, there are several brand-name natural desiccated thyroid drugs: Armour® Thyroid, Nature-Throid®, WP Thyroid®, and NP Thyroid®. (The FDA also designates NP Thyroid® as a generic equivalent to Armour® Thyroid.)

The U.S. Pharmacopeia (USP) sets manufacturing standards for medications. Per USP, 1 grain of natural desiccated thyroid is standardized at 65 mg. (Note that Nature-Throid® and WP Thyroid® 1 grain is 65 mg. Armour® Thyroid and NP Thyroid® have a different way of weighing ingredients, so 1 grain is 60 mg.)

1 grain of NDT needs to contain 38 mcg of T4 and 9 mcg of T3, and each tablet must contain no less than 90% and not more than 110% of the standardized T4 and T3 content

The following chart shows the dosage sizes for the four brands of NDT on the U.S. market:

Natural Desiccated Thyroid		
Nature-Throid MPThyroid Westhmid Pure	Armour* Thyroid (Thyroid Tablets, USP)	
DOSAGE SIZE	DOSAGE SIZE	
1⁄4 grain / 16.25 mg	1/4 grain / 15 mg	
½ grain / 32.5 mg	½ grain / 30 mg	
¾ grain / 48.75 mg	¾ grain / 45 mg	
1 grain / 65 mg	grain / 60 mg	
1¼ grain / 81.25 mg	1¼ grain / 75 mg	
1½ grains / 97.5 mg	1½ grains / 90 mg	
1¾ grains / 113.75 mg	1¾ grains / 105 mg	
2 grains / 130 mg	2 grains / 120 mg	
2¼ grains / 146.25 mg	21/4 grains / 135 mg	
2½ grains / 162.5 mg	2½ grains / 150 mg	
3 grains / 195 mg	3 grains / 180 mg	

6. Natural Desiccated Thyroid Brands

As noted, there are four brands of natural desiccated thyroid in the United States, dispensed only by prescription. They include:

- Armour® Thyroid
- Nature-Throid®
- WP Thyroid®
- NP Thyroid®

The FDA also designates NP Thyroid® as the "generic" NDT drug



Armour[®] Thyroid (Thyroid USP) Tablets



Armour[®] Thyroid is the best-known brand name NDT drug.

Website: www.armourthyroid.com, www.allergan.com/products/armour

Manufacturer: Was the Activis division of Allergan, and as of May 2020, Allergan was acquired by AbbVie



Manufacturer Website: www.abbvie.com

Prescribing information / Product Insert:
media.allergan.com/actavis/actavis/media/allergan-pdfdocuments/product-prescribing/06-2018-Armour-Thyroid-PI-final.pdf

Active Ingredient/API: Thyroid USP – source undisclosed.

Inactive Ingredients and Excipients: Calcium stearate, dextrose, microcrystalline cellulose, sodium starch glycolate, opadry white.



Nature-Throid® (Thyroid USP) Tablets



Nature-Throid[®] is an NDT drug first released (as Westhroid) in the 1930s, making it one of the first available medications for hypothyroidism. Nature-Throid[®] has been used safely for decades and never involuntarily recalled by the FDA. Nature-Throid[®] is designated as hypoallergenic and gluten-free and contains no artificial colors, artificial flavors, soy, yeast, egg, fish or shellfish, corn, peanut, or rice.

Website: www.naturethroid.com

Manufacturer: RLC Labs



Manufacturer Website: www.rlclabs.com

Prescribing information / Product Insert: getrealthyroid.com/assets/docs/Nature-Throid-Prescribing-Information.pdf

Active Ingredient/API: Thyroid USP – Specialty Process Labs, all North American animals, https://www.splabsglobal.com

Inactive Ingredients and Excipients: Colloidal Silicon Dioxide, Dicalcium Phosphate, Lactose Monohydrate (trace amounts found in all Thyroid USP), Magnesium Stearate, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Opadry II 85F19316 Clear.

Social Media: getrealthyroid.com, www.facebook.com/NatureThroid.WPThyroid, www.youtube.com/user/TheRLCLabs

Nature-Throi

WP Thyroid® (Thyroid USP) Tablets

Westhroid Pure

Westhroid Pure

WP Thyroid® is a specialized NDT drug, designed for enhanced absorption. The pills have no coatings and dissolve easily. WP Thyroid® limited excipients – chicory and coconut –come from natural sources, including chicory and coconut. (Some prescribers and patients report improved absorption and better control of thyroid levels.) WP Thyroid® is hypoallergenic and gluten-free, with no artificial colors, artificial flavors, soy, yeast, egg, fish or shellfish, corn, peanut, or rice. WP has been safely used since its start in the 1930s as Westhroid®. WP Thyroid® has never been involuntarily recalled by the FDA.

Website: http://www.wpthyroid.com

Manufacturer: RLC Labs

Manufacturer Website: www.rlclabs.com

Prescribing information / Product Insert: getrealthyroid.com/assets/docs/WP-Thyroid-Prescribing-Information.pdf

Active Ingredient/API: Thyroid USP – Specialty Process Labs, all North American animals, https://www.splabsglobal.com

Inactive Ingredients and Excipients: Inulin (derived from chicory root), Medium Chain Triglycerides (derived from coconut), Lactose Monohydrate (trace amounts found in all Thyroid USP)

Social Media: getrealthyroid.com, www.facebook.com/NatureThroid.WPThyroid, www.youtube.com/user/TheRL.instagram.com/npthyroid



NP Thyroid® / Thyroid USP Tablets / Generic NDT

Thyroid (Thyroid Tablets, USP)

NP Thyroid® is an NDT drug that the FDA designates as a generic equivalent for Armour® Thyroid. Prescriptions written for Thyroid USP or generic NDT are typically filled with NP Thyroid®. NP Thyroid® is gluten-free. In the Spring of 2020, batches of NP Thyroid® were found to have higher-than-specified amounts of T3, and 13 lots of the medication were voluntarily recalled due to this "superpotency" issue. Lots produced after May 2019 were not affected by this recall.

Website: www.npthyroid.com

Manufacturer: Acella

Manufacturer Website: www.acellapharma.com

Prescribing information / Product Insert: https://npthyroid.com/wp-content/uploads/2020/02/NP-Thyroid-flat-PI-10-15-19A-FPO.pdf

Active Ingredient/API: Thyroid USP – source undisclosed

Inactive Ingredients and Excipients: calcium stearate, dextrose (agglomerated), and mineral oil. Contains no ingredient made from a gluten-containing grain (wheat, barley, rye).

Social Media:

www.facebook.com/NPThyroid, www.twitter.com/npthyroid, www.instagram.com/npthyroid





7. Compounded Natural Desiccated Thyroid

A compounded medication is a drug that is mixed and prepared as a custom mix, specifically to meet your needs. Compounded natural desiccated thyroid is a prescription drug.

To make compounded NDT, a compounding pharmacy mixes Thyroid USP -- the Active Pharmaceutical Ingredient (API) –with fillers (excipients). This mixture is then put into capsules.

One of the variables in compounded NDT is the *source* of the API. Various compounding pharmacies get their Thyroid USP from different API manufacturers around the world. For example, some API is reportedly manufactured in China, where pharmaceutical regulations and environmental protections are lax, and product quality and purity are questionable. In some cases, API manufacturers outside the U.S. are sourcing their animals from undisclosed third countries—information not shared with patients.

That means that you can find it challenging to learn which API your compounding pharmacy is using, where the API is being manufactured, or where the pigs are raised.

If you want full disclosure on the API used in compounded NDT, you do have an option. A <u>network of compounding pharmacies in the U.S.</u> uses API sourced from Specialty Process Labs (SPL). SPL's Thyroid USP is the same API used to make Nature-Throid® and WP Thyroid® brand NDT. All the ingredients used in this API are sourced solely within North America, and the API itself is manufactured in the United States. You can be confident that these pharmacies provide compounded prescription hypothyroid medication that never leaves a highly regulated and monitored setting.

An Alternative to Nature-Throid® and WP Thyroid® Tablets

Patients taking the Nature-Throid® and WP Thyroid® brands of NDT have faced difficulties getting their medication in 2020 and 2021, due to FDA interference and recalls that have taken these drugs out of distribution for extended periods. (See Section 10 for details.) Unfortunately, many patients who, out of necessity switched to Armour® or NP Thyroid®, have reported a poor response to the substitutions and difficulty managing their hypothyroidism.

If you're a patient who feels best on Nature-Throid® or WP Thyroid® and you're not functioning well on a substitute brand, the API used by these other brands may be causing the problem.

If you want to get an NDT with a formulation closest to Nature-Throid® or WP Thyroid®, consider getting compounded NDT that uses the same API. As noted, the API is available from Specialty Process Labs (SPL). Foothills Pharmacy, a pharmacy based out of Arizona, provides high-quality compounded NDT -- using SPL's API -



- and other thyroid medications by mail-order across the U.S. For more information, see https://www.foothillspharmacy.com. A complete list of compounding pharmacies that use SPL's API Thyroid USP is available online at https://getrealthyroid.com/find-a-thyroid-pharmacy.html.

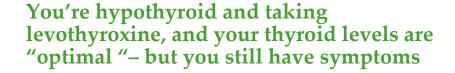
8. Do You Need Natural Desiccated Thyroid?

How do you know if you are one of the people with hypothyroidism who may feel better and have improved symptom relief while taking natural desiccated thyroid?

You may benefit from natural desiccated thyroid to treat your hypothyroidism if any of the following statements are true:









You take levothyroxine plus synthetic T3 (i.e., liothyronine or Cytomel), and you still have symptoms



You're a "low producer" – with low or lownormal Free T3 levels, and you still have symptoms



You're a "non-producer"- you don't have a working thyroid gland due to surgery, radioactive iodine, or congenital issues



You're "poor converter," with low or lownormal Free T3 (FT3) and/or high or highnormal Reverse T3 (RT3) levels, and you still have symptoms



You felt well in the past taking a natural desiccated thyroid drug, and since switching to levothyroxine, your symptoms have returned.



You prefer naturally derived drugs over synthetically-produced medications.



You can't afford levothyroxine plus liothyronine (or Cytomel) – or compounded T4/T3 combination – but you feel best on T4-T3 combination treatment

Note: Discuss with your health care provider whether natural desiccated thyroid drugs are right for you. Remember, however, that some conventional physicians and endocrinologists *only* prescribe levothyroxine. You may need to consult with a practitioner who includes NDT and T4/T3 combination therapy in their thyroid treatment options. (See Section 16 for help finding a practitioner.)

Natural desiccated thyroid drugs are not suitable if you have an allergy to pork products, don't eat pork for religious reasons, or are a vegetarian.

9. A Timeline and History of Natural Desiccated Thyroid

Before 1891: Before treatment was discovered and became routine, hypothyroidism could progress to severe myxedema: advanced hypothyroidism characterized by swelling, depressed breathing and low oxygen levels, mental slowness, and seizures.



Myxedema was usually fatal, typically taking about ten years from the diagnosis of myxedema to coma, and eventually, death from respiratory and heart failure.

1891: The first use of a thyroid extract – derived from the thyroid glands of sheep – was reported in the U.K. by Dr. George Redmayne Murray. Initially, thyroid extract was used for severe myxedema.

1891: First recorded use of thyroid extract in the U.S. Thyroid extract was not a mass-produced drug. Instead, it was produced by apothecaries – also known as chemists or druggists – who custom-prepared medications.

1890s to 1930s: Use of thyroid extract to treat hypothyroidism became widespread in Europe and the United States.



Dr. George Redmayne Murray

Early 1900s: The Armour Meat Packing company made Armour® Thyroid available to apothecaries as an ingredient for thyroid extract.

1920: Dr. George Redmayne Murray published a description of a patient successfully treated for almost 30 years with thyroid extract.

1934: Western Research Laboratories was founded by Dr. William McClymonds to manufacture and distribute the first commercially prepared and distributed natural desiccated thyroid drug, Westhroid.

1938: The new federal Food, Drug, and Cosmetic Act gave the Food and Drug Administration (FDA) oversight over various medications and established formalized approval processes. As an existing medication, natural desiccated thyroid was "grandfathered" and not required to go through any approvals.

1949: Levothyroxine (synthetic thyroxine) became commercially available. The FDA did not require new drug applications and approval at that time.

1960s – 1990s: Levothyroxine increasingly replaced the use of natural desiccated thyroid in the U.K. and U.S.

1966: A peak of 16.6 million prescriptions filled for NDT

1970: Armour and Company acquired by bus company Greyhound Corporation.

1978: Greyhound sold Armour (Pharmaceuticals division) to Revlon.

1981: Dennis Jones/Jones Medical Industries (JMI) acquired Western Research Laboratories from the McClymonds family.

1982: Nature-Throid® – a hypoallergenic version of Westhroid – was released by Western Research.

1985: Revlon sold its drug unit – including Armour® Thyroid – in 1985 to Rorer (later known as Rhône-Poulenc Rorer).

1988: 4.5 million prescriptions filled for NDT – Armour® Thyroid, Westhroid®, and Nature-Throid®.

1990 - 1997: The FDA reported <u>ten recalls of levothyroxine</u>, covering 150 different lots of medication and a total of 100 million tablets.

1991: Forest Laboratories acquired the rights to Armour® Thyroid from Rhône-Poulenc Rorer

1997: With 37 different manufacturers and repackagers of levothyroxine on the market, and widespread and ongoing problems with content uniformity, sub-potency, and stability, the FDA launched an effort to standardize levothyroxine sodium tablets and to minimize potency fluctuations. As a result,



the FDA declared levothyroxine sodium tablets a "new drug" and required new drug applications for approval of all levothyroxine drugs. (NDT was not included in this FDA ruling and remained grandfathered.)

1998: Western Research Laboratories was acquired by the Cox family: Rick, Judy, Lindsay, and Riki Cox.

1999 – 2001: Several companies submitted NDAs for levothyroxine, and the first product (Unithroid) was approved in August of 2000. Synthroid filed a citizen's petition to bypass the NDA process, but the FDA rejected that, and an NDA was ultimately filed for Synthroid.

2006: The name of Western Research Laboratories was changed to RLC Laboratories.

2013: A major study from Walter Reed National Military Medical Center found that 49% of patients preferred natural desiccated thyroid, compared to 18% who preferred levothyroxine – 33% had no preference. That study also found that patients who preferred natural desiccated thyroid had improved general well-being and significant improvement in thyroid

symptoms and lost approximately 4 pounds, compared to no weight loss or improvements in well-being and symptoms in the levothyroxine group.

2013: Acella introduced NP Thyroid® as a generic natural desiccated thyroid drug.

2013: WP Thyroid® released.

2014: A study published in the Journal of Endocrinology, Diabetes & Obesity was published. The study reported that, among patients who didn't feel well on levothyroxine, 78% who switched to natural desiccated thyroid said they preferred it.

2014-2015: Armour[®] Thyroid became an Allergan product with the merger of Forest Laboratories into Allergan in 2014-2015.

2017: Natural desiccated thyroid was the 130th most prescribed medication in the United States with around 5.5 million prescriptions per year (levothyroxine was the 3rd most prescribed drug, with almost 102 million prescriptions and refills).

2018: An American Thyroid Association survey of more than 12,000 people with hypothyroidism found that about 30% of patients take natural desiccated thyroid. The same survey found that patients had a higher level of satisfaction taking natural desiccated thyroid compared to levothyroxine.



2020: Pharmaceutical company AbbVie acquires Allergan, including Armour® Thyroid.

10. Natural Desiccated Thyroid: The Current Situation

Most thyroid patients taking natural desiccated thyroid (NDT) drugs in 2009 remember the FDA "crackdown" that year. Most generic versions of NDT drugs started to disappear off the shelves. At the same time, the FDA was ramping up its ominous threats to force "grandfathered" drugs -- drugs that never went through the new drug application (NDA) process -- to get formal FDA approval. (Grandfathered drugs were on the market before the FDA started approving drugs. Because these drugs were deemed essential, they were never taken off the market and/or forced to go through an approval process. They are considered FDA-regulated but not "FDA-approved" and remain legal to prescribe.)

At that time, it also looked and sounded like the FDA might actually pull ALL NDT drugs off the market and force them to go through the lengthy – and, in some cases, prohibitively expensive – process of filing an NDA.

Patients were NOT happy, to say the least, and I



spearheaded the creation of a vocal grassroots patient movement called "Save Natural Thyroid." Our goal was to make the FDA aware that we would not accept FDA action against an entire category of medication that millions of patients relied on daily for their hypothyroidism. The FDA backed down and shelved their plans for NDT drugs...for the time being.

But now, more than a decade later, it's looking like the FDA is back at it again, with plans to put thyroid patients at risk.

In early 2020, the FDA dramatically ramped up its inspections of selected NDT manufacturing facilities. There was no apparent reason for this crackdown. In May of that year, Acella, the small drug company that manufactures NP Thyroid®, ended up voluntarily recalling 13 lots of their NP Thyroid® tablets because the FDA found they were super-potent. That means that these lots of NDT were MORE potent than the stated dosage, and specifically, the extra potency was coming from the T3. Some patients had become hyperthyroid taking the super-potent NP Thyroid. These patients reported adverse effects, including symptoms of overmedication such as rapid heart rate. Acella was, however, allowed to continue distribution of the lots not listed by the FDA.

In September of 2020, Acella did another FDA-prompted voluntary recall, this time for sub-potency. Again, Acella was allowed to continue marketing the lots of medication that were not affected.

In early September of that year, RLC Labs – the other smaller company that manufactures two NDT drugs -- WP Thyroid® and Nature-Throid® -- voluntarily recalled 483 lots of these drugs due to FDA allegations of a minor sub-potency in only six lots.

The word on the street was that there had been no patient reports of any adverse effects, as the sub-potency was just a tiny fraction off of the required T4 level. The bigger question: Were these recalled lots sub-potent? That is highly unlikely.

The FDA could have given RLC an up-front opportunity to test specific lots in time to avoid a general recall, as they did for Acella. But that didn't happen. I suspect that the FDA may have threatened to strong-arm RLC with an involuntary recall – the kiss of death in the pharma world. To stay in business, RLC may have been forced to comply. So, thanks to the FDA, all the available stock of WP Thyroid® and Nature-Throid® got pulled out of distribution –making these drugs unavailable to the patients who

depend on them – until new batches can be manufactured, tested, and clear the FDA's questionable hurdles.

Here's another complication that the FDA introduced into the situation. The FDA warning letters to Acella and RLC also indicated that the FDA is changing the designation of NDT drugs to define them as "biologics."

Your products, which contain thyroglobulin (an alpha amino acid polymer with a specific defined sequence consisting of 2770 amino acids), are also biological products as defined in section 351(i)(1) of the Public Health Service Act (PHS Act), 42 U.S.C. 262(i)(1) because they are a "protein" as defined in 21 C.F.R. 600.3(h)(6), or are "analogous" to a protein because the identified biological product (i.e., protein) component in these naturally derived mixtures is necessary for the activity of the product and contributes to achieving the intended therapeutic effect.

Biologics are drugs that are derived from living cells. You've probably heard of other "biologics," like Botox, Humira, and Enbrel. I'll explain what this means in a moment.

I Have Questions!

Here's a recap. Three companies make NDT drugs in the U.S.: two are, as noted, small companies:

- Acella, which makes NP Thyroid®, has less than 200 employees and around \$120 million in annual revenue.
- RLC, which makes WP Thyroid® and Nature-Throid®, has less than 50 employees and around \$30 million in annual revenue.
- AbbVie, which makes Armour® Thyroid, employs about 30,000 people in 75 countries and has annual revenue of around \$30 *billion* a year. This global pharma behemoth also has massive armies of drug reps, marketing teams, and lobbyists on staff. Note that AbbVie only *recently* acquired Allergan and Armour.

My first question: Why is the FDA so interested in – and cracking down on –Acella and RLC, but NOT AbbVie?

And second: Given that NDT has been on the market for more than 100 years and is being used safely by millions of patients, why would the FDA make such a significant change in how NDT drugs are categorized, and only recently designate them as "biologics?"

These are important questions, and to date, we don't have definitive answers. But I have my own theory.

In addition to Armour® Thyroid – the best-known brand of NDT – AbbVie also manufactures the best-known brand of levothyroxine: Synthroid. And AbbVie also holds the rights to make and market Thyrolar (liotrix), a synthetic T4/T3 drug. Thyrolar is not currently being manufactured or on the market, but it could be at any time if AbbVie chooses to start back up. (Disclosure: Years ago, I took Thyrolar, and synthetic combo, with a T4/T3 ratio similar to NDT, worked well for me.)

The only category of thyroid hormone replacement AbbVie is not publicly involved in is synthetic T3 (liothyronine). Pfizer makes the brand name Cytomel, and there is also a generic version of liothyronine. (That said, who knows what else AbbVie may have in the pipeline? I wouldn't be surprised if they have a branded liothyronine in the pipeline, along with plans to resurrect Thyrolar – not to mention other thyroid meds –in the works.)

Price is also an issue. Synthroid is the highest-priced brand-name levothyroxine tablet. Armour® Thyroid has the highest retail price of any natural desiccated thyroid drug. AbbVie's two thyroid drugs are sometimes *more than double the cost* of other brand names.

My theory is that we need to follow the money.

Why is the FDA interested in – or cracking down on –Acella and RLC, but NOT AbbVie?

Follow the money.

There's an established pipeline of payments that go from pharma companies to FDA advisory and regulatory committees. Science

Magazine is one of many sources that have documented conflicts of interest between FDA advisors, who receive payments from big pharma companies before, during, and after drug reviews and approvals.



Smaller pharmaceutical companies like Acella and RLC don't have deep enough pockets to spread around that kind of money to FDA advisors.

Also, not a day goes by that AbbVie lobbyists aren't walking the halls of the FDA and in contact with FDA decision-makers. AbbVie even has its own political action committee – <u>AbbVie PAC – which donated almost \$1.5 million to candidates during the 2020 election cycle</u>.

As you would expect, small pharma companies don't have big teams of lobbyists.

There's another issue. Pharma companies sell each other "vouchers" that allow them to speed up the FDA approvals process. Back in 2015, <u>AbbVie paid another pharma company a record \$350 million</u> for a voucher that let them cut time off the FDA review process for a new drug. Will AbbVie buy a voucher to speed up biologics approval for Armour? It's pretty likely.

What does this all mean? Millions of people take natural thyroid drugs. But the two companies that make the far less expensive NDT drugs – and can't afford to lobby, pay FDA advisors, make political donations, and buy vouchers – are under siege by the FDA, and their products are being pulled off the market. Meanwhile, the pharma giant with the deep pockets – the one with the most expensive thyroid drugs -- appears to be getting a free pass.

AbbVie is in an enviable position. If the FDA officially declares NDT a "new drug," all the NDT drugs will have to go through the new drug application (NDA) approvals process. At the same time, during the NDA process, the FDA may:

- 1. require NDT drugs to go OFF the market entirely; or
- 2. allow NDT drugs to stay ON the market.

Option 1 would force millions of patients off NDT entirely, leaving them with only levothyroxine drugs for hypothyroidism treatment. (And, of course, many patients would end up taking AbbVie's Synthroid. AbbVie would still be selling medication to thyroid patients -- even as some of those patients suffer on a drug that doesn't work for them.)



If the FDA went with Option 2, this could also spell trouble. Acella and

RLC are already under targeted scrutiny by the FDA and dealing with their recalls. Trying to replace recalled product supply and manage a costly NDA process could potentially force them entirely out of the market. AbbVie, on the other hand, has not only been spared any recalls and FDA strong-arming but also has more than enough resources on hand to sail through the NDA process for Armour® Thyroid easily. The result? Armour® could easily end up the ONLY NDT on the market.

Is AbbVie positioning itself to have a monopoly on the NDT market and a near monopoly on thyroid treatment in general? Is the FDA actually helping them?!

If AbbVie succeeds at creating a monopoly, how much will the already high price of Synthroid and Armour® Thyroid increase? My guess is that prices will rise astronomically!

The Biologics Issue

As discussed, NDT has been on the market for more than 100 years and is used safely by millions of patients. So why designate this medication as a biologic now?

Again, *follow the money*. To be approved by the FDA, biologics have to go through an even more rigorous, expanded, lengthy -- and costly -- FDA approvals process that makes a standard NDA look like a breeze.

Not surprisingly, AbbVie already makes several "biologics" and has teams of lawyers, scientists, and lobbyists already in place to get a biologic drug approved. Unlike RLC and Acella, AbbVie makes biologic drugs, including Humira and Creon.

It's also worth noting that "biologics" are *very* expensive drugs. The familiar biologic, Botox, runs about \$500 to \$800 per treatment. AbbVie's Creon runs about \$1,700 a month. And the average monthly cost for AbbVie's Humira is around \$7,000 a month!

That raises another question. Whose idea was it to designate NDT as a

"biologic?" We don't have an answer, but I wouldn't be surprised if this decision resulted from intensive lobbying by AbbVie.

And, if the FDA goes forward with its plan to designate NDT as a biologic, what's likely to happen?



Armour® Thyroid will likely sail through the FDA process and get formal approval for Armour® Thyroid as a "biologic" thyroid hormone replacement drug. It's then likely that the retail price of Armour® could double or triple or worse. Armour® could end up costing hundreds -- or even thousands -- of dollars a month. Many insurance companies -- and Medicare -- don't even cover Armour® now. Even fewer would likely cover it at a significantly higher price. And how many patients would be able to afford it?

What Can You Do?

How well you do on a particular NDT drug depends on how it's formulated and the excipients, coatings, and disintegrants it uses. *It is not one-size-fits-all*. Some patients do well on Armour; others do best on Nature-Throid®, WP Thyroid®, or NP Thyroid®. Apart from my patient advocacy, I have a vested interest in ensuring that ALL the NDT options remain on the market and affordable because, in my case, I do best on the WP Thyroid. It has no coatings, and all the excipients are natural, so I have the best absorption and control on WP Thyroid. Unfortunately, since 2020, we've faced severe shortages of some dosages of NP Thyroid® and the unavailability of WP Thyroid® and Nature-Throid® brands.

Patients – including me – have been forced to take NDT brands that don't work for them and pay higher prices. And given the situations I've been telling you about, it's likely to get worse into 2022.

Patients and practitioners need to speak up, loudly and consistently, to protect our right to take the natural desiccated thyroid drug of our choice. Otherwise, we risk having only Armour® Thyroid at potentially unaffordable prices.

Speaking Up About NDT

If you want to protect your right to take the NDT of your choice, here are some things you can do.

1. Contact the FDA!

Start by contacting the following people at the FDA:

- Dr. Shawn Larson at 214-253-5216, email Shawn.Larson@fda.hhs.gov
- William Millar at (503) 671-9711 Ext. 30, email william.millar@fda.hhs.gov
- Tamala Bogan, email <u>Tamala.bogan@fda.hhs.gov</u>
- Steven Porter, Jr., email steven.porter@fda.hhs.gov

Note: Be sure to CC all emails to ORAPHARM2 Responses@fda.hhs.gov

Call and complain to the FDA main consumer line at 1-888-INFO-FDA (1-888-463-6332)

Call the FDA Consumer Complaint Division for your region: https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators

2. Report Adverse Effects

If you are forced to take a thyroid drug that doesn't work for you, and you have any adverse effects, be sure to report them to the FDA's Medwatch System for Adverse Effects. You can do this online at



https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

3. Flood the FDA on Social Media!

Don't forget to FLOOD the FDA on social media to express your concerns. Natural desiccated thyroid drugs have been prescribed safely for a century and are an effective and affordable treatment option for millions of people with hypothyroidism. Tell the FDA to LEAVE OUR NDT DRUGS ALONE! You'll find the FDA on Twitter at https://twitter.com/US FDA and Facebook at https://www.facebook.com/FDA

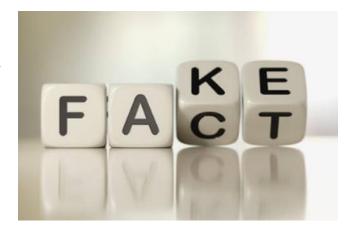


4. Stay Informed

Finally, be sure to check back at www.naturalthyroidguide.com for news and updates on further action steps you can take. And make sure you www.naturalthyroidguide.com for news and updates on further action steps you can take. And make sure you www.naturalthyroidguide.com for news and updates on further action steps you can take. And make sure you www.naturalthyroidguide.com for the latest updates.

11. Natural Desiccated Thyroid: Myths and Controversies

If you've asked your doctor to prescribe natural desiccated thyroid (NDT), you may have gotten – or may get – pushback. That's because, among many endocrinologists and conventional physicians, NDT is considered controversial. Some doctors are misinformed about NDT. And, some doctors refuse even to discuss NDT or prescribe it, or only prescribe it reluctantly.



What's going on? Patients took NDT for more than 50 years, and it's again regaining popularity. But here are some of the issues, myths, misinformation, and controversies surrounding NDT you might encounter.

"NDT is too old fashioned"

Many practitioners dismiss natural desiccated thyroid and "too old-fashioned." The reality is that NDT was the first – and only – treatment for hypothyroidism from the late 1800s until the 1950s. NDT drugs have been safely used as an effective hypothyroidism treatment for more than 100 years. Like NDT, other "old-fashioned drugs" like aspirin (1890s) and penicillin (1920s) are also still in widespread use, alongside newer medications.



"There's no difference, so you should just take levothyroxine"

Some doctors say that all thyroid hormone replacement is the same, so you might as well take levothyroxine.

The truth is that NDT and levothyroxine are very different.

NDT is derived from the dried thyroid glands of pigs and has T4, T3, and other cofactors like T1, T2, and calcitonin. Levothyroxine is a synthetic version of just the T4 hormone.



Levothyroxine treatment relies on the belief – *proven wrong* – that everyone can convert T4 into T3 effectively and in needed amounts to resolve hypothyroidism.

"Levothyroxine controls thyroid levels better than NDT" and "Levothyroxine is more effective than NDT"

Some practitioners claim that levothyroxine is more effective than NDT and better at controlling hypothyroidism and thyroid test levels.

Recent studies, however, show that a significant percentage of hypothyroid patients taking levothyroxine have abnormal test levels and continued symptoms. Interestingly, numerous studies also show that a majority of patients prefer NDT over levothyroxine



"NDT is not FDA-approved"

NDT was in use long before the U.S. Food and Drug Administration (FDA) was created. As a result, NDT was among many necessary drugs that were "grandfathered" in and not required to go through what's called the new drug application (NDA) process for FDA approval. It was and continues to be legal to prescribe NDT for hypothyroidism.



When levothyroxine was first introduced, it was also grandfathered by the FDA because the manufacturers claimed it was similar to NDT. Between 1990 and 1997, there were ten levothyroxine recalls, affecting 100 million tablets, made by 37 different manufacturers and repackagers of levothyroxine. The FDA identified widespread and ongoing problems with content uniformity, sub-potency, and stability failures in levothyroxine drugs.

As a result, the FDA undertook an effort to standardize levothyroxine tablets and reduce potency problems. In August of 1997, the FDA declared levothyroxine sodium tablets a "new drug." Going forward, anyone who wanted to continue marketing levothyroxine needed to submit a New Drug Application (NDA) or file a petition describing why an NDA was not necessary.

Between June 1999 and July 2001, several companies submitted NDAs, and the first product (Unithroid) was approved in August of 2000. The FDA rejected Synthroid's petition to bypass the NDA process, and an NDA was ultimately filed for Synthroid, which was eventually approved. Currently, several FDA-approved brand-name levothyroxine drugs and generic equivalents are available in the United States.

So, while NDT is not "FDA-approved," it *is* FDA-regulated. And, because NDT is an FDA-regulated drug, manufacturers must adhere to FDA guidelines that standardize natural desiccated thyroid production and meet potency and consistency standards or face FDA recall.

"NDT is not consistent!"

Decades ago, the potency and consistency of NDT were standardized based on its iodine content. Basing NDT on iodine resulted in some issues with potency fluctuations. Unfortunately, some practitioners wrongly believe these same concerns still apply, years after changes.

The reality? NDT manufacturers must follow FDA guidelines on "Good Manufacturing Practice," and these drugs are standardized based on the T4 and T3 content.

Specifically, a 1 grain (60 or 65 mg) tablet needs to contain 38 mcg T4 and 9 mcg T3 with a margin of error of plus or minus 10%. The measured amount of T4 and T3 in NDT tablets must be between 34.2 and 41.8 mcg of T4 and 8.1 to 9.9 mcg of T3.

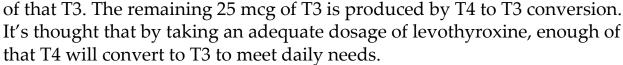


Manufacturers are required to ensure that their medications meet those standards throughout each lot's expiration date.

"You don't need T3!"

Many conventional physicians and endocrinologists believe that treatment with T3 – the active thyroid hormone – is rarely necessary and that T4 treatment (levothyroxine) is sufficient. Their rationale is that a normal thyroid gland does not produce the required daily amount of T3. Instead, The T3 is made when the T4 hormone is converted into T3 by "deiodination" – also known as T4 to T3 conversion. In this process, the T4 hormone loses an iodine molecule to become T3.

The typical daily T3 requirement in a 154 pound (70 kg) healthy adult is around 30 mcg. The thyroid gland itself produces around 5 mcg

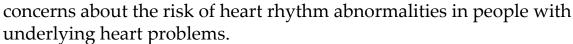


Experts are now beginning to understand, however, that this is not the case for everyone. Some cutting-edge researchers have identified genetic defects – known as "polymorphisms" – that make T4 to T3 conversion less effective in some people. Antonio Bianco, MD, Ph.D. – director of Bianco Lab at the University of Chicago – has conducted groundbreaking research on the issue. Dr. Bianco concluded that as many as 15% of people with hypothyroidism might have these genetic defects, which cause them to need treatment with T3 to achieve healthy thyroid hormone levels and relieve hypothyroidism symptoms.

"It's dangerous! T3 levels are too high on NDT!"

As discussed, T3 levels peak within 2 to 6 hours after taking NDT. That means that those patients tend to have higher T3 levels than those taking levothyroxine. Some experts have concerns regarding the stimulatory effects of those higher T3 levels on the heart, including the risk of atrial fibrillation. There are also concerns regarding T3's impact on bone density and the potential to increase the risk of fractures.

Specifically, the professional associations, medical societies, and government agencies also designate natural desiccated thyroid as "high risk" for people aged 65 and older due to



Interestingly, various studies have found that at appropriate doses, NDT normalizes thyroid levels and eliminates the signs and symptoms of hypothyroidism similarly to levothyroxine, with no adverse side effects, including heart-related symptoms. There is currently no evidence that fluctuations in T3 within the normal reference range, with normal TSH levels, constitute a risk factor.



"T3/T4 ratios are too high on NDT!"

When it comes to T3 and T4 levels:

- Most patients who take NDT have a much higher T3/T4 ratio
- Patients who take NDT have T3 levels that peak between two to six hours after taking their medication. The peak depends on the dose taken but can go as high as 40 to 80% above baseline T3 levels and continue for several hours



Some doctors point to the T3/T4 ratio and higher peak T3 levels as reasons not to prescribe NDT. This is not a scientifically supported conclusion, however. The data from all published clinical trials (studying around 1000 patients for up to a year), and an observational study of 400 patients over nine years, do not show increased risk or health complications in patients taking NDT compared to levothyroxine.

"I only prescribe levothyroxine!"

Because levothyroxine replaced NDT in the 1960s as the preferred thyroid treatment, several generations of physicians have limited training, a poor understanding of, and minimal clinical experience prescribing NDT. As a result, they also have little experience managing patients on NDT drugs.

Many of these practitioners simply avoid prescribing NDT rather than learning how to prescribe and treat patients with NDT correctly.



"Levothyroxine is the only 'accepted' treatment" and "My medical society doesn't support the use of NDT"

All the professional thyroid associations and medical societies in the U.S. – including the American Thyroid Association and the American Association of Clinical Endocrinologists – have issued guidelines stating that patients should initially be treated only with levothyroxine. Only when those patients clearly have not benefited should a T4/T3 treatment be tried. Even then, the societies typically recommend combination therapy of levothyroxine with synthetic T3 (liothyronine) rather than NDT.



Research shows that NDT is an effective and safe treatment option for most patients with hypothyroidism. It should be noted that some of the largest levothyroxine manufacturers are providing financial support to these associations and medical societies, and their physician members.

"You'll get mad cow disease!"

Here's a ridiculous claim made by some doctors. They have stated in public that "NDT is made from cows and can cause mad cow disease." This is total misinformation. All NDT drugs in the U.S. are porcine (from pigs). And no cases of "mad cow disease" have been associated with NDT drugs.



"NDT is not a prescription drug"

Some truly uninformed practitioners claim that NDT is an over-the-counter supplement that doesn't require a prescription. This is incorrect. NDT medications require a doctor's prescription, and NDT is NOT an over-the-counter supplement.

(This misinformation was even actively promoted in the past by the Ralph Nader-founded group Public Citizen's "Worst Pills, Best Pills" newsletter, which condemned NDT, claiming it was a supplement!)





12. Conversion Chart: Natural Desiccated Thyroid, Levothyroxine, and Liothyronine/T3

The following conversion chart shows the dosage equivalents between different natural desiccated thyroid drugs (NDT), levothyroxine (synthetic T4), and liothyronine (synthetic T3).



Here's something to understand: The U.S. Pharmacopeia (USP) sets quality, purity, strength, and identity

standards for medicines, food ingredients, and dietary supplements. USP has developed "Reference Standards" for all drugs. According to the <u>USP</u> <u>Reference Standards for Natural Desiccated Thyroid</u>, 65 mg (1 grain) of natural desiccated thyroid needs to contain no less than 90 percent and not more than 110 percent of the labeled amounts of 38 mcg of T4 and 9 mcg of T3.

Nature-Throid® and WP Thyroid® use the USP Reference Standard of 65 mg for a 1 grain tablet weight. (Armour® and generic NP Thyroid® list their pills as 60 mg for 1 grain.)

If you have a prescription written for 60 or 90 or 120 mg of NDT, you can fill it with Armour® or NP Thyroid®, but *not* Nature-Throid® or WP Thyroid®. If your prescription is written for 1, 1 1/2, or 2 grains of NDT, you should be able to fill it with *any* NDT drug.

Note: This conversion chart is only a *general* guideline. If you switch from levothyroxine to NDT, *your* optimal dose of NDT is likely to differ from this general conversion chart. The right dose of NDT for you depends on many factors, including absorption, T4-to-T3 conversion, and other factors.

Natural Desico	cated Thyroid	Levothyroxine/T4	Liothyronine/T3
Nature-Throid You, improved. Westhroid Pure	Armour* Thyroid (THYROID TABLETS, USP) N GRAN.—S GRAN PThyroid* (Thyroid Tablets, USP)	Synthroid. (Levothyroxine sodium tablets, USP) Levoxyl Indique uden tablet. 32 Trosint-SOL Jevothyroxine uden tablet. 32	Cytomel
DOSAGE SIZE	DOSAGE SIZE	DOSAGE SIZE	DOSAGE SIZE
¼ grain / 16.25 mg	1/4 grain / 15 mg	25 mcg	5 mcg
½ grain / 32.5 mg	½ grain / 30 mg	50 mcg	
¾ grain / 48.75 mg	¾ grain / 45 mg	75 mcg	
		88 mcg	
1 grain / 65 mg	1 grain / 60 mg	100 mcg	25 mcg
		112 mcg	
1¼ grain / 81.25 mg	1¼ grain / 75 mg	125 mcg	
	NAME STATE	137 mcg	
1½ grains / 97.5 mg	1½ grains / 90 mg	150 mcg	
1¾ grains / 113.75 mg	1¾ grains / 105 mg	175 mcg	
2 grains / 130 mg	2 grains / 120 mg	200 mcg	50 mcg
2¼ grains / 146.25 mg	2¼ grains / 135 mg		
2½ grains / 162.5 mg	2½ grains / 150 mg		
3 grains / 195 mg	3 grains / 180 mg	300 mcg	



13. Natural Desiccated Thyroid Prescriptions and Substitutions

As noted, the USP standards specify that specify that:

- 1 grain of natural desiccated thyroid is 65 mg
- 1 grain/65 mg needs to contain no less than **90**% and not more than **110**% of the standardized T4 and T3 content and potency.
- 1 grain/65 mg is standardized at 38 mcg of T4 and 9 mcg of T3.

Nature-Throid® and WP Thyroid® use the USP Reference Standard of 65 mg for a 1 grain tablet. RLC has voluntarily set its own tighter manufacturing standard of 95% to 105% potency.

Armour® and NP Thyroid® list their pills as 60 mg for 1 grain.

Because Nature-Throid®/WP
Thyroid® use the 65 mg/1 grain standard – and Armour® and NP
Thyroid® use the 60 mg/1 grain standard – you can run into some difficulties when filling your prescription depending on how



it is written. Technically, because of the milligram differences, Nature-Throid® and WP Thyroid® **are not interchangeable** with Armour® Thyroid and generic NP Thyroid®.

If your prescription is written for **grains** of NDT, you should be able to fill it with *any* brand name or generic natural desiccated thyroid drug.

If your prescription is written for Nature-Throid® or WP Thyroid® in mg, technically, it can only be filled with one of these two medications. Armour® Thyroid (or generic NP Thyroid®) are not considered equivalent to Nature-Throid® and WP Thyroid®.

If your prescription is written for Armour® Thyroid (or generic NP Thyroid®), they are considered equivalent to each other.

The following chart summarizes the grains and milligrams for the different NDT drugs.

Natural Desiccated Thyroid			
Nature-Throid MPThyroid Westhroid Pure	Armour* Thyroid (Thyroid Tablets, USP)		
DOSAGE SIZE	DOSAGE SIZE		
1/4 grain / 16.25 mg	1/4 grain / 15 mg		
½ grain / 32.5 mg	½ grain / 30 mg		
¾ grain / 48.75 mg	¾ grain / 45 mg		
1 grain / 65 mg	grain / 60 mg		
1¼ grain / 81.25 mg	1¼ grain / 75 mg		
1½ grains / 97.5 mg	1½ grains / 90 mg		
1¾ grains / 113.75 mg	1¾ grains / 105 mg		
2 grains / 130 mg	2 grains / 120 mg		
21/4 grains / 146.25 mg	21/4 grains / 135 mg		
2½ grains / 162.5 mg	2½ grains / 150 mg		
3 grains / 195 mg	3 grains / 180 mg		

Prescriptions

How your prescription is written can determine which medication pharmacies can use to fill it:

- A prescription written for Natural Desiccated Thyroid in grains can be filled with any NDT drug.
- Prescriptions for NDT for 65 mg, 130 mg, etc., can be filled with Nature-Throid® and WP Thyroid®.
- Prescriptions for NDT for 60 mg, 120 mg, etc., can be filled with Armour[®] Thyroid or generic NDT (NP Thyroid[®])
- If a prescription is written for Nature-Throid® or WP Thyroid®, it can be filled with either of these drugs.
- If a prescription is written for Armour® Thyroid, it can also be filled with generic NDT (NP Thyroid®.)



Preventing Pharmacy Substitutions

Pharmacies frequently attempt to substitute natural desiccated thyroid drugs improperly. If your pharmacy is trying to make substitutions that aren't right for you, ask your doctor to write the prescription in a way that **prohibits** any substitution. That means your prescription should carry one of the following statements or checked instructions:

- Brand Medically Necessary
- No Substitution
- Substitution Not Allowed
- DAW or Dispense as Written





14. Natural Desiccated Thyroid: **Costs and Savings**

How much are you paying – and should you pay – for your natural desiccated thyroid (NDT) medication? Here are a few essential pointers:

- Armour® Thyroid is the most expensive NDT drug. (There is no apparent reason why other than name recognition.)
- Acella's NP Thyroid® is designated as a generic equivalent to Armour® Thyroid, is significantly less expensive, and is considered equally safe and effective as Armour®.
- RLC's Nature-Throid® is the best value when it's available, with the lowest prices available from multiple sources.
- Prices for compounded NDT vary significantly, depending on the pharmacy. You can pay anywhere from around \$40 a month to as much as \$100 a month for compounded NDT.
- Be careful about pharmacies that tell you they don't have your prescribed NDT drug
- available and attempt to substitute another brand. Some pharmacies receive financial incentives for promoting specific brands.
- Always check both GoodRx and SingleCare for discount prices because they have different coupons and savings, and they can change frequently.

- Mail-order pharmacies can be a cost-saving option for some NDT medications.
- Always ask your pharmacist which is less: the retail price or your price with an insurance copay. (The retail cash price is *frequently* lower than your copay, but you won't know unless you specifically ask.)

Prices as of October 2021 GoodR ◆ SingleCare honeybee







Armour[®] Thyroid

Average Retail Price: \$39

The prices are taken from GoodRx, which creates an average of retail prices from retailers, including pharmacies (CVS, Walgreens, etc.) and other pharmacies (Walmart, Kroger, Publix, Costco, etc.)

GoodRx Lowest Price: \$32

GoodRx Order/Info: https://www.goodrx.com/armour-thyroid

SingleCare Lowest Coupon Price: \$32

SingleCare Order/Info: <a href="https://www.singlecare.com/prescription/armour-prescri **thyroid**

HoneybeeHealth Price: \$39

Honeybee Order/Info: https://honeybeehealth.com/drugs/armour-thyroid

NP Thyroid® / Generic Natural Desiccated Thyroid Costs

Average Retail Price: \$31

These prices are taken from GoodRx, which creates an average of retail prices from retailers, including pharmacies (CVS, Walgreens, etc.) and other pharmacies (Walmart, Kroger, Publix, Costco, etc.)

GoodRx Lowest Price: \$11

GoodRx Order/Info: https://www.goodrx.com/np-thyroid

SingleCare Lowest Coupon Price: \$32

SingleCare Order/Info: https://www.singlecare.com/prescription/np-

thyroid

HoneybeeHealth Price: \$36

Honeybee Order/Info: https://honeybeehealth.com/drugs/np-thyroid

Compounded NDT

The price of a one-month supply of NDT can vary widely depending on the compounding pharmacy you use. Prices typically range from around \$30 up to \$100. It's recommended that you reach out to several reputable compounding pharmacies to compare prices.

I also recommend that you get pricing from Foothills Pharmacy. This Arizona-based compounding pharmacy provides mail order service across most states in the U.S. and typically has excellent pricing. You can learn more about Foothills at https://www.foothillspharmacy.com.

15. Starting and Taking Natural Desiccated Thyroid

When you're starting or taking natural desiccated thyroid, here are some guidelines to keep in mind:

- You should take natural desiccated thyroid (NDT) in the morning, ideally on an empty stomach, at least 30 to 60 minutes before eating breakfast.
- It's recommended that you take NDT with a glass of water.
- Experts also recommend you wait at least an hour after taking your NDT before drinking coffee or milk because both beverages can negatively affect absorption.
- Antacids that include calcium, aluminum hydroxide, magnesium, iron and calcium supplements, multivitamins containing iron or calcium, and beverages like calcium-fortified juices can also affect NDT absorption. You should take NDT four hours before or after these medications, supplements, or drinks.



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

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





The absorption of all thyroid medications, including NDT, can be negatively affected by gastrointestinal and digestive conditions such as Crohn's disease, celiac disease, reflux/GERD, and ulcers. Be sure to discuss these conditions with the practitioner treating your hypothyroidism.

Some Additional Considerations About How You Take NDT

- Because the T3 in NDT peaks rapidly (within 2-6 hours) in the bloodstream, some patients have better results with a divided dosage, taking half the prescribed dosage in the morning and a half in the afternoon.
- Some patients do best when taking some or all of their NDT at bedtime. Be aware, however, that the stimulatory effect of the T3 in NDT can interfere with sleep in some patients.
- Some patients and practitioners anecdotally report better absorption when NDT tablets are allowed to dissolve under the tongue or chewed rather than taken with water.

Keeping Your Provider Informed

When taking NDT, make sure to tell the provider if you:

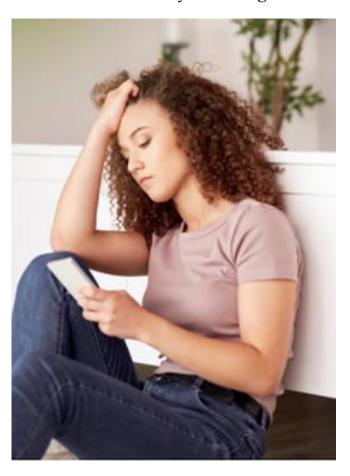
- have any allergies to foods, additives, medicines, or supplement allergies
- are pregnant, trying to conceive, or breastfeeding
- are already taking any prescription or over-the-counter medications or supplements
- start or stop any prescription or over-the-counter medications or supplements
- suffer from any medical conditions other than hypothyroidism, especially heart disease, clotting disorders, or adrenal or pituitary gland problems
- have diabetes
- are taking anticoagulants (blood thinners)



Contact Your Provider When...

Contact your healthcare provider right away if you experience any of the following symptoms while being treated with thyroid hormone replacement medication, including natural desiccated thyroid drugs

- rapid or irregular heartbeat
- chest pain
- shortness of breath
- leg cramps
- headache
- nervousness
- irritability
- sleeplessness
- tremors
- vomiting
- diarrhea
- excessive sweating
- heat intolerance
- fever
- hives
- skin rash
- other unusual signs or symptoms



16. Finding Natural Desiccated Thyroid-Friendly Healthcare Practitioners

One challenge you may face is finding a health care provider willing to prescribe natural desiccated thyroid (NDT) and manage patients treated with NDT.

Among M.D.s, endocrinologists are less likely to be open to prescribing NDT. Holistic or integrative MDs, a friendly and involved general practitioner, or even a gynecologist may be your best choice.

Remember that you're not limited to working with just an M.D. Your ideal healthcare provider needs to be able to prescribe. That means you may find that your best choice



is a naturopathic physician (an ND), an osteopathic physician (a DO), a nurse practitioner (NP), or a physician assistant (PA).

If you are interested in finding an NDT-friendly health care provider, here are some helpful starting places.

Find a Thyroid Doctor - from RLC Labs

https://getrealthyroid.com/find-a-thyroid-doctor.html

FIND A THYROID DOCTOR

Recommended Doctor List - from ThyroidChange

http://www.thyroidchange.org/patient-recommended-doctor-list-us.html



Hypothyroidism Telemed Clinic - Paloma Health

If you are looking for a new doctor, one effective option to consider is working with Paloma Health; the only virtual medical practice focused on hypothyroidism patients. Virtual visits are available with thyroid-savvy physicians in many states served by Paloma – with more states added all the time. For more information, see www.palomahealth.com



Ask for Referrals

You can also ask for referrals to NDT-friendly providers in your area, from:

- local natural pharmacies or health food stores
- trusted providers, such as nutritionists or acupuncturists
- friends or coworkers who already work with integrative or thyroid-savvy providers



Practitioner Databases

There are a variety of databases and lists online to help you identify integrative, holistic, and open-minded practitioners. (Keep in mind that you should always verify that the provider is open to working with NDT medications ahead of time.)

 American College for Advancement in Medicine — Integrative Physician Finder http://acam.site-ym.com/search/custom.asp?id=1758v



- Lifescript's Doctors Who Treat or Diagnose Hormonal Imbalance http://www.lifescript.com/doctor-directory/condition/h-hormonal-imbalance.aspx
- The American College for Advancement in Medicine's Physician+Link - Integrative Doctor Database http://acam.site-ym.com/search/custom.asp?id=1758
- The International College of Integrative Medicine's ICIM Member Search
 - http://www.icimed.com/member_search.php
- American Board of Integrative Holistic Medicine Database http://www.aihm.org/search/custom.asp?id=4620
- American Association of Naturopathic Physicians Find a Naturopathic Doctor Database https://naturopathic.org/search/custom.asp?id=5613

17. Order Your Own Thyroid and Other Lab Tests

If high-co-pays, disinterested doctors, or insurance and HMO restrictions are preventing you from getting the tests you need, you have the power to take charge of your health care!

Accurate and easy home bloodspot thyroid test kits -- and lab tests at local Quest labs -- are available at *significantly* discounted costs, with no doctor's



appointment or lab request from your doctor needed.

Some popular tests you can order directly include:

- Comprehensive thyroid panel, including TSH, Free T4, Free T3
- Reverse T3, Thyroid Antibodies, Iodine
- Adrenal Stress/Saliva Cortisol
- HA1C and Leptin (for weight loss)
- Ferritin (for hair loss)

and much more. Learn more now!

https://www.mary-shomon.com/order-tests

Paloma Home Thyroid Test Kit

Online medical practice Paloma Health offers an at-home thyroid test kit. The kit provides comprehensive, highly accurate test results from a CLIA-certified lab and is available for \$99. The kit tests:

- TSH
- Free T4
- Free T3
- Thyroid Peroxidase Antibodies

Add-ons are available at checkout to add tests for:

- Vitamin D
- Reverse T3

Paloma's at-home test kits let you test wherever you are, including the comfort of home.



All you need to do is...

- 1. Order your test kit, which is shipped to you quickly, free.
- 2. Complete a blood test. (It's a fast, easy, and painless finger prick!)
- 3. Mail back your test card in the prepaid mailer.
- 4. Get your results back in days, delivered securely online.

Visit Paloma now to order your at-home test.

Lab Tests with Ulta



Did you know that in most states in the U.S., you can order your own lab tests without a doctor's visit or a doctor's lab order? It's called "direct-to-consumer" laboratory testing, and I'm making this service available to you, as an independent contractor of <u>Ulta Lab Tests</u>.

With Ulta, you have access to thousands of medical tests at significantly lowered costs -- often much lower than your insurance copays! You can usually pay for testing out of health savings accounts (HSA) as well. It's an affordable and convenient way to privately learn about your health.

The Benefits

- You eliminate the cost and inconvenience of a doctor's visit just to order routine testing
- Bypass doctors, HMOS, and insurers that refuse your request for specific tests
- Tests cost as much as 80% less than in your doctor's office or local hospital lab and may even be less than copays
- Complete privacy and security for your medical records; your test results are never added to your insurance or HMO files (unless you add them)
- Access to a private, personal health record online
- Get testing for vitamin and mineral levels to help monitor your response to supplements and dietary changes
- You are in control of your health

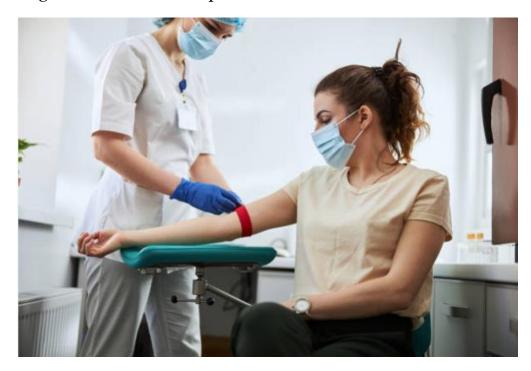
How it Works

It's simple to use Ulta Lab Tests!

- 1. Find the tests you want, and order and pay for them at <u>Ulta Lab Tests</u>.
- 2. Go to a convenient lab for testing.
- 3. When your results are in, you'll get an email from Ulta.
- 4. View or download your results on your secure patient portal and share them with your physician. It's that easy!

(Note: Due to state laws, Ulta cannot provide their services in N.J., NY, or R.I.)

Visit https://www.ultalabtests.com/shomon to see my custom panels and the full range of Ulta Lab Test options.



Individual Tests from Ulta

Thyroid / Thyroid Antibodies / Thyroid-Related

Thyroid Stimulating Hormone (TSH)

Free T4 (FT4)

Free T3 (FT3)

Reverse T3 (RT3)

Thyroid Peroxidase Antibody (TPO)

Thyroglobulin Antibody (TgAb)

Thyroid Stimulating Immunoglobulin (TSI) Iodine, 24-hour Urine

Blood Sugar/Weight

Fasting Glucose (Blood Sugar)

Hemoglobin A1C (HbA1c)

Leptin Test

Autoimmune Diabetes

Fasting Glucose (Blood Sugar)

Hemoglobin A1C (HbA1c)

C-Peptide Test

Glutamic Acid Decarboxylase (GAD Antibodies)

Adrenal Issues

Saliva Cortisol (4 samples) Test

Adrenal Stress Complete Panel

DHEA Sulfate

Nutritional Status

Vitamin D, 25 Hydroxy Test

Ferritin Test

About Mary Shomon

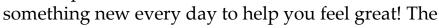
Mary Shomon is an internationally-known patient advocate, writer, health coach, and a *New York Times* and Amazon.com bestselling author of 15 books on health and wellness.

Here are some resources Mary has created to help you truly live well!

Mary Shomon's Thyroid Support Group on Facebook



Join more than 130,000 thyroid patients across the world, all seeking effective solutions and better health! Ask questions, share experiences, and learn



group is located at www.facebook.com/ThyroidSupport



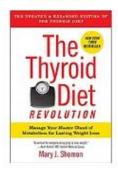


Do you have questions, need to map out customized approaches and plans, understand your bloodwork, lose weight, get your hair back, find a new doctor, or understand your thyroid and hormonal health in a new way? Set up a personal, one-on-one telephone coaching session with Mary Shomon. More information is available at www.mary-shomon.com/coaching.

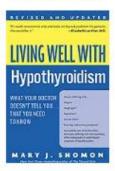
Books from Mary Shomon

For details, see www.mary-shomon.com/books

Thyroid Diet Revolution



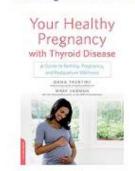
Living Well with Hypothyroidism



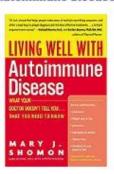
Hair Loss Master Plan



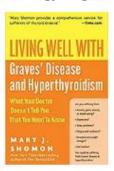
Your Healthy Pregnancy with Thyroid Disease



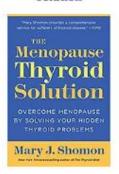
Living Well with Autoimmune Disease



Living Well with Graves' Disease & Hyperthyroidism



Menopause Thyroid Solution



Living Well with Chronic Fatigue & Fibromyalgia



Free Email Newsletter

Subscribe to *Sticking Out Our Necks*, Mary Shomon's free email newsletter on thyroid and hormonal health – in publication for more than two decades! You can subscribe at www.mary-shomon.com/subscribe or https://hormones.substack.com

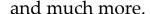


The Thyroid Tuneup

If you still don't feel well on your thyroid treatment, you need a Thyroid Tuneup. The 2021 Thyroid Tuneup program includes a 3-part online, on-

demand video workshop, which explains everything you need to know about optimizing your thyroid treatment. Topics covered include:

- reference/normal ranges vs. optimal ranges for thyroid tests
- all your treatment options
- antibodies and autoimmunity
- Reverse T3
- adrenal and sex hormone imbalances
- foods and supplements that can help your thyroid



In addition to the on-demand videos, the program includes a full-length book, the 2021 Thyroid Tuneup Owner's Manual. The program also includes four free gifts:

- Full-length Thyroid Meditation MP3 audio program
- The Two-Week Energy Overhaul Guide
- Thyroid Thin Guide
- Hair, Brows and Lashes Guide

You can learn more about the program and get your copy at https://maryshomon.podia.com/thyroidtuneup



The Levothyroxine Deep Dive Educational Program



COMPLETE

I've created a comprehensive and free educational program providing in-depth information about levothyroxine drugs – including brands and generics, costs, patient programs, and troubleshooting.

The Levothyroxine Deep Dive includes an online informational website, an on-demand video webinar series, and a downloadable eBook guide, all available at no cost. You'll find the complete Levothyroxine Deep Dive at https://www.mary-shomon.com/dive.

The Thyroid Deep Dive Podcast

The Thyroid Deep Dive Podcast is a free podcast covering thyroid disease. My goal for the podcast is to dive into important thyroid-related topics from a patient perspective. The podcast -- featuring patients, advocates, physicians, and experts from all facets of conventional and integrative health – shares life-changing and innovative information that will help you truly feel and live well with a thyroid condition in 2021 and beyond!

You can subscribe and listen to the Thyroid Deep Dive at all your favorite podcast platforms/apps.

- Apple Podcasts: Thyroid Deep Dive
- Spotify: Thyroid Deep Dive
- Google Podcasts: Thyroid Deep Dive
- Stitcher: Thyroid Deep Dive
- TuneIn: Thyroid Deep Dive

In addition to the podcast platforms, you can also listen to the promo trailer and the full episodes at the podcast website. The website also has full-text episode transcripts, along with resources and links.

You can also sign up for free email updates about the podcast! You'll find it all online at www.thyroiddeepdive.com.

