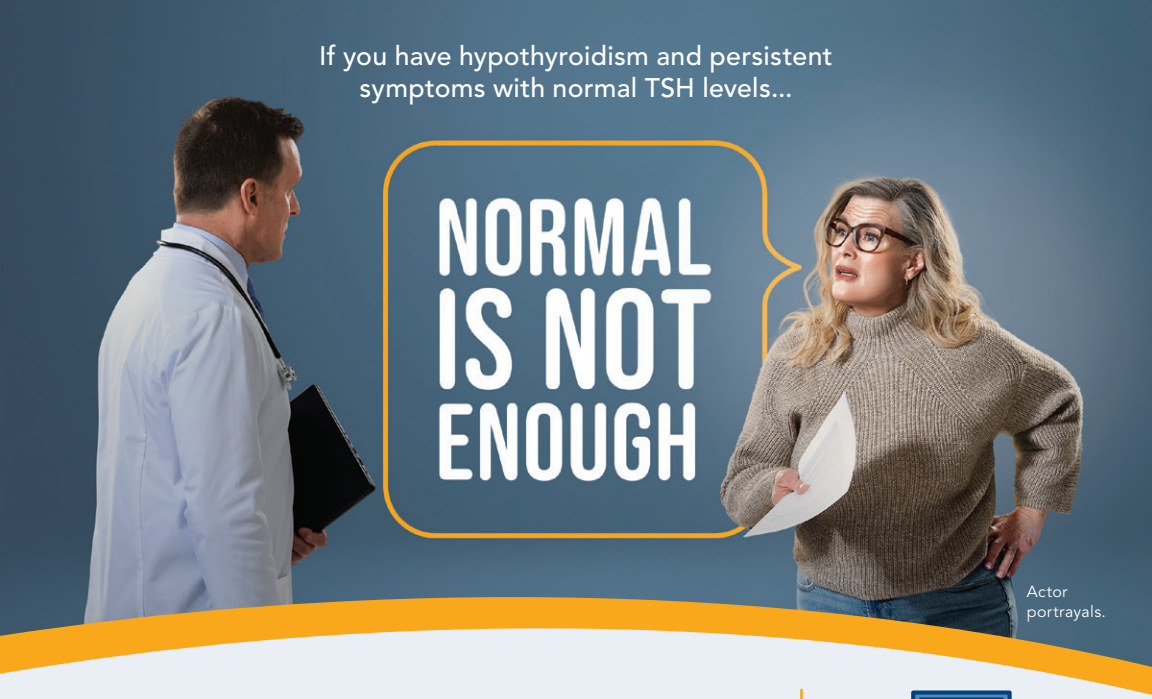

Getting started on TIROSINT® Capsules

This guide provides information and resources to help you get started on treatment with TIROSINT (levothyroxine sodium) Capsules for hypothyroidism. **If you have questions or concerns about your medication or how you are feeling, please talk with your doctor.**

TSH=thyroid-stimulating hormone.

Visit TIROSINT.com to learn more.

USE

TIROSINT® (levothyroxine sodium) Capsules is a prescription medicine that contains a man-made hormone called levothyroxine which replaces a hormone that is normally produced in your body by the thyroid gland. It is meant to replace the hormone to treat a condition called hypothyroidism. TIROSINT is not for use in people with temporary hypothyroidism caused by thyroiditis or inflammation of the thyroid gland.

Who should not use TIROSINT:

TIROSINT is not recommended to treat benign thyroid growths or enlargement of the thyroid gland in patients with sufficient iodine levels.

IMPORTANT SAFETY INFORMATION

NOT FOR TREATMENT OF OBESITY OR FOR WEIGHT LOSS

Thyroid hormones, including TIROSINT, should not be used either alone or in combination with other medications for the treatment of obesity or for weight loss.

In patients with normal thyroid levels, doses within the range of daily hormonal requirements are not helpful for weight loss.

Larger doses may result in serious or even life threatening events, especially when used in combination with certain other medications to reduce appetite.

Please see Important Safety Information on pages 8 and 9 and click here for Full Prescribing Information, including BOXED WARNING.

Tirosint®
(levothyroxine sodium) capsules

The goals of treatment

Treatment for hypothyroidism involves replacing or providing more of the thyroid hormone that your own thyroid can no longer make.

As part of your treatment journey, your doctor will sometimes have you do blood tests to monitor your levels of thyroid hormone (T4) and thyroid-stimulating hormone (TSH). The goal is to get these lab values to within a normal range.

But lab values are not the only measure of treatment success: Even when lab values are normal, some people with hypothyroidism have symptoms that continue to disrupt their lives. Addressing these symptoms is another important goal of treatment.

Common symptoms of hypothyroidism can include:

Constipation

Dry, coarse, brittle hair

Dry, itchy skin

Hair loss

Less energy/more fatigue/ need for more sleep

Loss of appetite

Memory problems/ slow thinking

Muscle cramps and joint aches

Pins and needles in the hands and feet

Puffiness of the face, hands, ankles, and feet

Snoring

Weight gain/difficulty losing weight

This is not a complete list. These may be symptoms of hypothyroidism and you may have other symptoms that may be related to hypothyroidism. **If you have concerns about any of the symptoms you are experiencing, please talk with your doctor.**

Please see Important Safety Information on pages 8 and 9 and click here for Full Prescribing Information, including BOXED WARNING.

TIROSINT® Capsules— what's inside your medicine

Most medicines used to treat hypothyroidism are levothyroxine (LT4) tablets. In addition to the active ingredient levothyroxine, tablets may also contain inactive ingredients that can sometimes cause stomach irritation or make it harder for some people to absorb their medicine.

TIROSINT is not a tablet. TIROSINT Capsules is a gel capsule form of levothyroxine that contains only 4 ingredients. It does not contain other ingredients that might interfere with how your body absorbs or responds to it.

Unique gel-cap formulation with
only 4 ingredients

Actual size

	TIROSINT Capsules	LT4 Tablets*
LEVOTHYROXINE	✓	✓
GLYCERIN	✓	
GELATIN	✓	
WATER	✓	
LACTOSE		✓
CONFECTIONER'S SUGAR		✓
POVIDONE		✓
TALC		✓
ACACIA		✓
MAGNESIUM		✓
COLOR ADDITIVES		✓

This table provides information about ingredients only and does not imply any comparisons about how safe or effective a medication is. This is not a complete listing of all approved medicines for hypothyroidism.

*Ingredients may vary based on formulation.

LT4=levothyroxine.

TIROSINT® Capsules—precise dosing for *you*

At the start of treatment, your doctor will work with you to find your daily dose of TIROSINT Capsules. This will be an individualized dose based on your age, weight, heart health status, and other factors, and the goal is to find the dose that gets your TSH levels to within normal range. TIROSINT Capsules offers 15 dosage strengths, giving your doctor a wide range of options to choose from to prescribe a precise dose for you.

TIROSINT Capsules is available in cartons containing 30 capsules each

The packaging is designed with visual cues so you and your pharmacy can easily confirm that you receive a carton with the dosage strength you have been prescribed.

100 mcg per capsule

Each dosage strength has a unique color code that is visible on the front of the carton.

K

Each TIROSINT capsule is imprinted with a dosage-strength–specific letter code.

Each TIROSINT capsule is contained in an individual "well" labeled with the dosage strength.

Please see Important Safety Information on pages 8 and 9 and click here for Full Prescribing Information, including BOXED WARNING.

Available in 15 doses with color-coded packaging

13 mcg	25 mcg	37.5 mcg
44 mcg	50 mcg	62.5 mcg
75 mcg	88 mcg	100 mcg
112 mcg	125 mcg	137 mcg
150 mcg	175 mcg	200 mcg

TIROSINT is made in a facility that is dedicated to

TIROSINT production only

so there is no risk of cross-contamination with other products.

Actor portrayal.

What you should know about taking TIROSINT® Capsules

When you are prescribed TIROSINT, your doctor will give you instructions on how and when to take it. It is important that you take TIROSINT Capsules as directed. **Please talk with your doctor if you have any questions about taking TIROSINT.**

How to take TIROSINT Capsules

- Take TIROSINT exactly as your doctor tells you to take it.
- **You should swallow TIROSINT gel capsules whole.** Do not crush, cut, or chew the capsules before swallowing them. If you or your child have difficulty swallowing the capsules whole, tell your doctor.
- **Do not** remove TIROSINT capsules from the original blister package until you are ready to take them.
- Take your prescribed dose of TIROSINT only one time each day, 30 minutes to 1 hour before breakfast, on an empty stomach.

Certain medicines can interfere with how your body absorbs TIROSINT

You should take TIROSINT:

At least 4 hours before or after you take medicines that contain calcium carbonate or iron (such as oral iron supplements, calcium supplements, antacids)

At least 4 hours before you take medicines that contain bile acid sequestrants or ion exchange resins

Know the medicines you take. Ask your doctor or pharmacist if you are not sure if any of the medicines you take may contain these ingredients. This is not a complete list of all possible medicines that can interfere with TIROSINT. Talk with your doctor or pharmacist before starting or stopping any medicines.

Please see Important Safety Information on pages 8 and 9 and click here for Full Prescribing Information, including BOXED WARNING.

Certain foods may affect the way your body absorbs TIROSINT

Tell your doctor if you regularly eat these foods, as they may require your dose of TIROSINT to be adjusted.

These include:

- Soybean flour
- Cottonseed meal
- Walnuts
- Dietary fiber
- Grapefruits or grapefruit juice

Actor portrayals.

Your doctor will do certain blood tests to monitor your progress while you are taking TIROSINT and may change your daily dose of TIROSINT as needed.

You should not stop taking TIROSINT or change your dose unless your doctor tells you to.

Tell your doctor if you become pregnant or plan to become pregnant while taking TIROSINT.

USE

TIROSINT® (levothyroxine sodium) Capsules is a prescription medicine that contains a man-made hormone called levothyroxine which replaces a hormone that is normally produced in your body by the thyroid gland. It is meant to replace the hormone to treat a condition called hypothyroidism. TIROSINT is not for use in people with temporary hypothyroidism caused by thyroiditis or inflammation of the thyroid gland.

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Thyroid hormones, including TIROSINT, should not be used either alone or in combination with other medications for the treatment of obesity or for weight loss.

In patients with normal thyroid levels, doses within the range of daily hormonal requirements are not helpful for weight loss.

Larger doses may result in serious or even life threatening events, especially when used in combination with certain other medications to reduce appetite.

Do not take more TIROSINT than your doctor prescribes. Overdosage or taking too much TIROSINT may cause life-threatening side effects or death.

TIROSINT should not be used by children less than 6 years of age or who cannot swallow an intact capsule. TIROSINT is also not for use in people with temporary hypothyroidism caused by thyroiditis or inflammation of the thyroid gland.

Do not take TIROSINT if your adrenal glands are not working well and you have not been treated with glucocorticoid replacement for this problem.

What is the most important information you should know about TIROSINT?

TIROSINT is a prescription medicine that contains a man-made hormone called levothyroxine which replaces the hormone that is normally produced in your body by the thyroid gland. It is used to treat adults and children 6 years of age and older:

- To replace or give extra levothyroxine in people whose thyroid gland does not naturally produce enough (a condition called hypothyroidism).
- Who need surgery and radioiodine therapy to manage a type of thyroid cancer called thyroid-dependent well-differentiated thyroid cancer.

Before you take TIROSINT, tell your healthcare provider about all your medical conditions, including if you: Currently have or have previously had heart problems; currently have or have previously had thyroid nodules; have kidney or pituitary gland problems; have any food or drug allergies; have a low red blood cell count; have diabetes; have weak or weakening bones (osteoporosis); currently have or have previously had a history of blood clotting problems.

Also tell your healthcare provider if you are pregnant or planning to become pregnant, or are breastfeeding. TIROSINT may harm your unborn baby. Your doctor may need to change your TIROSINT dose while you are pregnant. TIROSINT passes into breast milk. Talk to your doctor about the best way to feed your baby if you take TIROSINT.

Please see Important Safety Information on pages 8 and 9 and click here for Full Prescribing Information, including BOXED WARNING.

It is important that you tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. TIROSINT may affect the way other medicines work, and other medicines may affect how TIROSINT works. Ask your doctor or pharmacist for a list of medicines that may interact with TIROSINT.

Certain foods may affect the way that your body absorbs TIROSINT. These include:

- Soybean flour
- Cottonseed meal
- Walnuts
- Dietary fiber
- Grapefruits or grapefruit juice

Tell your healthcare provider if you regularly eat these foods, as they may require your dose of TIROSINT to be adjusted.

Important information about taking TIROSINT:

You should take TIROSINT exactly as your doctor tells you to take it. Your doctor will tell you how much TIROSINT to take each day. You should not stop taking TIROSINT or change your dose unless your doctor tells you to.

Take TIROSINT once each day, on an empty stomach, approximately 30 minutes to 1 hour before breakfast.

Certain medicines can interfere with how TIROSINT is absorbed by your body. Take TIROSINT: **At least 4 hours before or after** you take medicines or supplements that contain calcium or iron (ferrous sulfate, ferrous fumarate, etc.); and **at least 4 hours before** you take medicines that contain bile acid sequestrants or ion exchange resins. Ask your doctor if you are not sure whether any medicines you are taking may contain these ingredients. Your doctor should do certain blood tests while you are taking TIROSINT and may change your daily dose of TIROSINT as needed.

What are the possible side effects of TIROSINT?

The most common side effects of TIROSINT include irregular heartbeat, chest pain, shortness of breath, leg cramps, headache, nervousness, irritability, sleep problems (insomnia), tremors, muscle weakness, change in appetite, weight loss, vomiting, diarrhea, sweating a lot, heat intolerance, fever, changes in menstrual period, and hives or skin rash.

TIROSINT may cause serious side effects, including heart problems. Your risk for these problems may be greater if you are elderly, have heart problems, or if you take too much TIROSINT. Tell your doctor right away if you develop heart problems, as your doctor may choose to reduce your dose or stop treatment with TIROSINT.

TIROSINT may also cause worsening of blood sugar control in diabetic patients and weak or brittle bones. Tell your doctor if you are diabetic or if you already have weak or brittle bones (osteoporosis) before taking TIROSINT.

Partial hair loss may occur during the first months of treatment with TIROSINT. This is usually temporary and lasts a short period of time.

USE ONLY AS DIRECTED BY YOUR HEALTHCARE PROFESSIONAL. These are not all the possible side effects of TIROSINT. Talk to your healthcare provider or pharmacist for more information or for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or by visiting www.fda.gov/medwatch. For more dosing information, please click here for Full Prescribing Information and Patient Information.

Tirosint®
(levothyroxine sodium) capsules

TIROSINT® DIRECT PROGRAM

Save with TIROSINT® Direct

Actor portrayal.

With TIROSINT Direct, you can get a **low out-of-pocket cash price for your TIROSINT prescription*** and have it delivered to your home when you order from a network of participating mail-order pharmacies.

*Terms, conditions, and eligibility restrictions apply.
Please visit **www.Tirosint.com** for full terms and conditions.
A Medicare Part D Letter is also available on this website.

Easy access

TIROSINT Direct works for people with or without health insurance. Order from one of our participating mail-order pharmacies to save money.

Transparent pricing

You can be confident that you will pay a low out-of-pocket cash price for your TIROSINT prescription based on your individual circumstances. Contact a participating pharmacy to ask about the current cost of your prescription.

Flexible supply

Get up to 180 days (6 months) of therapy at a time. Note that the price is based on a single carton containing 30 gel capsules (a 1-month supply).

Available doses and fast delivery

Our participating pharmacies stock all doses, and they are available for immediate delivery. In most cases, your medication will arrive within 2 to 3 business days after your order has been processed. You'll also receive reminders when it's time to refill your prescription.

Payment options

Major credit cards are accepted. You can get a receipt to submit to your Flexible Spending Account (FSA) or Health Savings Account (HSA) administrator, or to your health insurance provider.

To learn more about TIROSINT Direct and find a participating pharmacy, please click here. You can also ask your doctor if they know about TIROSINT Direct.

Please see Important Safety Information on pages 8 and 9 and click here for Full Prescribing Information, including BOXED WARNING.

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Tirosint® (levothyroxine sodium) capsules