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Tirosint-Sol

# **Tirosint-Sol**

Pronunciation: tee-row-sent-sōl Generic name: levothyroxine (T4) Dosage form: oral solution Drug class: Thyroid drugs

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## What is Tirosint-Sol?

Tirosint-Sol is an oral levothyroxine (L-thyroxine [T4]) solution that may be used in adults and children, including neonates:

- to replace or give extra levothyroxine in people whose thyroid does not produce enough of this hormone; or
- with surgery and radioiodine therapy to manage a type of thyroid cancer called thyroid-dependent well-differentiated thyroid cancer.

Tirosint-SOL is a synthetic (man-made) T4 hormone that is converted by deiodination in peripheral tissues to T3, which binds at a much greater affinity than T4 to thyroid receptor proteins attached to DNA. T3 is responsible for most of the physiological actions of thyroid hormones (such as controlling metabolism, heart rate, temperature, and digestion). Tirosint-Sol exerts the same effects in the body as T4 and is made naturally, maintaining normal T4 levels when a deficiency is present.

Tirosint-Sol is a unique formulation of levothyroxine that comes as a pleasant-tasting liquid and is supplied in a small ampoule which is taken by mouth (orally). It only contains only 3 ingredients — levothyroxine, glycerol, and water — unlike levothyroxine tablets, which often contain several inactive ingredients such as wheat starch (gluten), lactose, sugars, dyes, and talc.

Tirosint-Sol (oral solution) was FDA approved on December 15, 2016, following the approval of Tirosint capsules on October 13, 2006. It is FDA-approved for patients of any age.

# **Warnings**

Do not take it if you are allergic to levothyroxine (the active ingredient) or glycerol (an inactive ingredient) in Tirosint-Sol or if your adrenal glands are not working well and you have not been treated for this problem.

Do not use Tirosint-Sol to treat obesity or for weight loss. Severe and life-threatening side effects may happen if it is taken in large doses or with other drugs for weight loss. Talk with your healthcare provider.

The dosage of Tirosint-Sol is individualized for each patient. Do not take more or less than what is recommended and do not share your medication with others.

There is a risk of cardiovascular adverse events, including atrial fibrillation, associated with Tirosint-Sol, the risk is higher in the elderly and in patients with underlying cardiovascular disease.

Do not use oral thyroid hormone drug products to treat myxedema coma (a rare and severe complication of low thyroid levels). It should not be used to treat people who are recovering from swelling of the thyroid gland (thyroiditis) and whose bodies do not produce enough levothyroxine for a short time.

Patients in acute adrenal crisis with concomitant adrenal insufficiency should be treated with replacement glucocorticoids before starting Tirosint-Sol treatment.

May worsen blood sugar control in those with diabetes mellitus, requiring an increase in the dosage of insulin or antidiabetic medications. Carefully monitor your blood sugar levels after starting, changing, or discontinuing thyroid hormone therapy.

Thyroid replacement therapies have been associated with decreased bone mineral density. Over-replacement can increase bone resorption and decrease bone mineral density. Your doctor will individualize your dosage for you. Never share your medicine with other people.

# **Before taking**

Before taking Tirosint-Sol, tell your doctor about all of your medical conditions, including if you:

- · have or have had heart problems
- have or have had thyroid nodules
- · have adrenal or pituitary gland problems
- · have any food or drug allergies
- have low red blood cell count (anemia)
- · have diabetes
- have weak bones (osteoporosis)
- · have or had a history of blood clotting problems
- have recently received radiation therapy with iodine (such as I-131)
- · are pregnant or plan to become pregnant
- · are breastfeeding.

This medicine may affect fertility and affect your ability to get pregnant or father a child. Talk to your doctor about this.

# Pregnancy

Your doctor may need to increase your Tirosint-Sol dose while you are pregnant. If you have hypothyroidism, your healthcare provider should measure your serum TSH and free-T4 as soon as your pregnancy is confirmed and, at minimum, during each trimester of pregnancy, and increase the dosage as recommended in the prescribing information to maintain serum TSH in the trimester-specific reference range.

## **Breastfeeding**

Tirosint-Sol can pass into breast milk but no adverse effects on the breastfed infant have been reported and adequate levothyroxine treatment during lactation may normalize milk production in hypothyroid lactating mothers with low milk supply. Talk to your doctor about the risks versus benefits of taking Tirosint-Sol while breastfeeding.

Tirosint-Sol pregnancy and breastfeeding warnings (more detail)

## How should I take Tirosint-Sol?

Tirosint-Sol is for oral use only. Do not inhale, inject, or place it in the eyes.

- Take it exactly as your doctor tells you to take it. Your doctor will tell you how much to take each day. Your doctor may change your dose if needed. Always check the dosage on the ampule to make sure you have the correct dose.
- Take your dose of Tirosint-Sol once a day, 15 minutes before breakfast. It is for oral use only do not inhale, inject,
  or place in the eyes.

You can take Tirosint-Sol:

- By directly squeezing it into the mouth or onto a spoon
- By diluting or mixing it with water first. Do not mix it with anything other than water. Once you have mixed it, take it immediately. Do not store for future use. If you do not take it immediately, throw it away.

When you are ready to take your dose, open the aluminum pouch by tearing along the edge along the dotted line. Remove 1 ampule from the strip. Return the unused ampules to the pouch.

- Open the ampule by twisting off the top. Ensure you squeeze the pouch at least 5 times to remove all of the liquid.
- Certain medicines can interfere with how Tirosint-Sol is absorbed by your body. Take it at least 4 hours before or after you take medicines that contain calcium carbonate or iron (ferrous sulfate); and at least 4 hours before you take medicines that contain bile acid sequestrants or ion exchange resins.
- Certain foods including soybean flour, cotton seed meal, walnuts, and dietary fiber can affect your treatment and dose of Tirosint-Sol. Talk to your doctor if you eat or drink these foods.

Your doctor should do certain blood tests while you are taking Tirosint-Sol and may change your daily dose as needed. Keep taking it unless your doctor tells you to stop or to change your dose.

It may take weeks before you notice your symptoms getting better. Keep using this medicine even if you feel well. Do not run out of Tirosint-Sol.

Detailed Tirosint-Sol dosage information

# What happens if I miss a dose?

Take a missed dose as soon as you think about it.

If it is close to the time for your next dose, skip the missed dose and go back to your normal time.

Do not take 2 doses at the same time or extra doses.

# What happens if I overdose?

If you take too much Tirosint-Sol, call your doctor, or the Poison Control Center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

## What are the side effects of Tirosint-Sol?

Tirosint-Sol may cause serious side effects, including:

- signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever;
   wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- heart problems. You may experience an increased heart rate, chest pain, and irregular heartbeat. Your risk of
  developing heart problems may be greater if you are elderly, you have heart problems, or you take too much. Your
  doctor may reduce your dose or stop treatment for a while if you develop heart problems.
- worsening diabetic control. If you are diabetic, it may be harder to control your blood sugar levels causing
  hyperglycemia while taking Tirosint-Sol. Check your blood sugar levels closely after starting, changing, or stopping
  treatment with Tirosint-Sol. Your doctor may have to change your diabetes treatment plan.
- weak or brittle bones. Your risk of developing weak or brittle bones may be greater if you are post-menopausal or you take too much Tirosint-Sol.

The most common side effects of Tirosint-Sol include:

- · fast or irregular heartbeat
- irritability
- vomiting
- · chest pain
- sleep problems (insomnia)
- diarrhea
- · shortness of breath
- tremors
- · sweating a lot
- leg cramps
- muscle weakness
- heat intolerance
- headache
- · change in appetite
- fever
- nervousness
- · weight loss

- changes in menstrual periods
- · hives or skin rash.

Other side effects may include partial hair loss during the first months of treatment. This usually only lasts a short period (temporary).

This medicine may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.

These are not all the possible side effects of TIROSINT-SOL. Call your doctor for medical advice about side effects. You may report side effects to IBSA Pharma Inc. at 1-800-587-3513 or the FDA at 1-800-FDA-1088

1 Tirosint-Sol side effects (more detail)

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# What other drugs will affect Tirosint-Sol?

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take Tirosint-Sol (levothyroxine oral solution) with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor. Take Tirosint-Sol

- at least 4 hours before or after you take medicines that contain calcium carbonate or iron (ferrous sulfate)
- at least 4 hours before you take medicines that contain bile acid sequestrants or ion exchange resins.

Some foods like soybean flour (infant formula) may change how Tirosint-Sol (levothyroxine oral solution) works in your body. Talk with your doctor.

If you drink grapefruit juice or eat grapefruit often, talk with your doctor.

Know the medicines you take. Ask your doctor or pharmacist for a list of these medicines, if you are not sure. See the prescribing information for a full list of interactions.

Tirosint-Sol drug interactions (more detail)

## Does Tirosint-Sol interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Tirosint-Sol
+
Enter a drug name
Add

# **Storage**

Store Tirosint-Sol in the original pouch at room temperature, 20°C to 25°C (68 °F to 77°F). Store in a dry place. Do not store in a bathroom. Protect from heat and light.

Use within three (3) months after opening the pouch. Keep the ampules in the pouch until ready to use as important information may be lost (such as manufacturer/distributor names and contact phone numbers).

Do not store the diluted or mixed solution.

Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets. Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Ask your pharmacist when the next Drug Take Back day is.

# Ingredients

Active ingredient: levothyroxine sodium.

Inactive ingredients: glycerol, and water.

Available in 15 different strengths: 13 mcg/mL, 25 mcg/mL, 37.5 mcg/mL, 44 mcg/mL, 50 mcg/mL, 62.5 mcg/mL, 75 mcg/mL, 88 mcg/mL, 100 mcg/mL, 112 mcg/mL, 125 mcg/mL, 137 mcg/mL, 150 mcg/mL, 175 mcg/mL, 200 mcg/mL.

Each box contains 6 pouches. Each pouch contains 5 ampules.

Do not remove Tirosint-Sol ampules from the sealed aluminum foil pouch until you are ready to use them.

## **Manufacturer**

IBSA Pharma Inc.

# **Popular FAQ**

Does levothyroxine cause weight gain or loss?	~
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How long does levothyroxine stay in your system?	~
What is the difference between Levoxyl and Synthroid?	~
What is the difference between Unithroid and Synthroid?	<b>~</b>

#### More FAQ

• How soon after taking levothyroxine can I take omeprazole?

#### References

1. Product Label

# More about Tirosint-Sol (levothyroxine)

- · Check interactions
- · Compare alternatives
- · Pricing & coupons
- Reviews (7)
- Latest FDA alerts (1)

- · Side effects
- Dosage information
- During pregnancy
- FDA approval history
- Drug class: thyroid drugs
- Breastfeeding
- En español

### **Patient resources**

#### Other brands

Synthroid, Tirosint, Euthyrox, Levoxyl, ... +3 more

## **Professional resources**

- Tirosint-Sol prescribing information
- Levothyroxine (AHFS Monograph)

### Other brands

Synthroid, Tirosint, Euthyrox, Levoxyl, ... +5 more

# Related treatment guides

- Hashimoto's disease
- Underactive Thyroid
- TSH Suppression

## **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

### **DRUG STATUS**

### **Availability**

Rx Prescription only

### **Pregnancy & Lactation**

ন্ড Risk data available

#### **CSA Schedule\***

N/A Not a controlled drug

**Approval History** 

### **User Reviews & Ratings**

7 Reviews

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