TIROSINT® (levothyroxine sodium)

This leaflet is intended for use with levothyroxine sodium capsules, tablets, and oral solution.

HIGHLIGHTS OF PRESCRIBING INFORMATION
CONTRAINDICATIONS
Contraindicated in a patient with a known hypersensitivity to levothyroxine or any of its excipients.

NURSING MOTHERS
It is not known whether levothyroxine is excreted in human milk. Because many drugs, including thyroid hormones, are excreted in human milk, caution should be exercised when levothyroxine is administered to a nursing woman.

PREGNANCY
Pregnancy Category C

PATIENT COUNSELING INFORMATION
The following instructions are intended for the patient or caregiver:
- Follow the dosage and medical instructions provided by your healthcare provider.
- Swallow capsules whole; do not cut, crush, or chew.
- Take at the same time every day, preferably before breakfast, and at least 4 hours apart from any medication that interferes with absorption.
- Do not take with other medications that interfere with absorption.
- If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose.
- Do not take double doses.
- Store at room temperature.

ADVERSE REACTIONS
 potential for medication interactions.

DRUG INTERACTIONS

TIROSINT is not indicated for suppression of benign thyroid nodules and contains no iodine.

Suppression

• TIROSINT is not indicated for suppression of well-differentiated thyroid cancer.

• Take levothyroxine sodium in the morning before breakfast (2.1) for best absorption.

• Swallow capsules whole; do not cut, crush, or chew.

• Oral solution may be used in patients who cannot swallow capsules.

• TIROSINT is supplied in tablets containing 25 mcg, 50 mcg, 75 mcg, 100 mcg, 125 mcg, 150 mcg, 200 mcg, and 250 mcg levothyroxine sodium (as sodium salt) and is available in 500-count bottles.

• TIROSINT is supplied in 125 mcg capsules, 88 mcg capsules, and 44 mcg capsules.

• TIROSINT is supplied in 125 mcg tablets, 88 mcg tablets, and 44 mcg tablets.

• TIROSINT contains active ingredient levothyroxine sodium (as sodium salt).

• Tablet strength and capsule strength information is provided in Table 2.

• Adults and children: Start with the full replacement dose as determined by your healthcare provider.

• Use of oral thyroid hormone drug products is not recommended with sympathomimetic amines such as those used for their vasoconstrictive effects.

• Oral solution is supplied in 125 mcg strength in 88 mcg concentration in 15-ml bottles and 44 mcg concentration in 5-ml bottles.

• Oral solution contains active ingredient levothyroxine sodium (as sodium salt).

• Oral solution is supplied in bottles containing 15 ml of 88 mcg oral solution and 5 ml of 44 mcg oral solution.

• Oral solution contains no color, flavor, or preservatives.

• Oral solution is supplied in 15-ml bottles labeled "oral solution."
Pregnancy
Since postpartum TSH levels are similar to preconception levels, it is important to monitor TSH levels in women who are pregnant or planning to become pregnant. Consult your healthcare provider for advice on TSH monitoring during pregnancy.

Experience with levothyroxine use in pregnant women, including those with hypothyroidism, has not revealed a teratogenic risk. However, studies involving pregnant women are limited. As a precaution, it is recommended that levothyroxine use during pregnancy be performed only under the supervision of a healthcare provider who is accustomed to dealing with this condition.

If you are pregnant, planning to become pregnant, or are breast-feeding, consult your healthcare provider before taking levothyroxine. Levothyroxine should be used cautiously during pregnancy and breastfeeding. Consult your healthcare provider for guidance on managing thyroid hormone levels during pregnancy and breastfeeding.

Common side effects may include:
- Nausea
- Diarrhea
- Abdominal pain
- Muscle cramps
- Fatigue
- Fast heart rate
- Tingling sensations
- Headache
- High blood pressure

Less common side effects may include:
- Rash
- Itching
- Seizures
- Changes in menstrual periods
- Changes in mood or behavior

If you notice any of these side effects or if your symptoms do not improve, contact your healthcare provider immediately.

Instruct patients not to take levothyroxine within 4 hours of these medications due to decreased absorption:
- Oral contraceptives
- Pimozide
- Quinidine
- Rifampin
- Other medications containing efavirenz, non-nucleoside reverse transcriptase inhibitors, or protease inhibitors

If you are taking levothyroxine, you should notify your healthcare provider of any changes in your medications or medical conditions. This is particularly important if you are taking other medications that may affect thyroid hormone levels, such as interferons or oral contraceptives.

Instruct patients to notify their healthcare provider if they have any of these conditions:
- Recent radiation therapy
- Recent surgery
- Recent illness
- Recent weight gain or loss
- New or worsening symptoms

If you are taking levothyroxine, you should also notify your healthcare provider of any changes in your medications or medical conditions. This is particularly important if you are taking other medications that may affect thyroid hormone levels, such as interferons or oral contraceptives.

If you have any questions or concerns about levothyroxine or its use, please contact your healthcare provider.

To report side effects, you may contact the FDA MedWatch program at 1-800-FDA-1088 or visit www.fda.gov/medwatch. You may also contact the Levothyroxine Levothroid Manufacturer at 1-800-222-1222 or www.poison.org.