



MercuryPharma

PATIENT INFORMATION LEAFLET

Levothyroxine 50 and 100 micrograms Tablets Levothyroxine Sodium

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The product is known by the name above but will be referred to as Levothyroxine Tablets throughout the rest of this leaflet.

In this leaflet:

1. What Levothyroxine Tablets are and what they are used for
2. Before you take Levothyroxine Tablets
3. How to take Levothyroxine Tablets
4. Possible side effects
5. How to store Levothyroxine Tablets
6. Further information

1. What Levothyroxine Tablets are and what they are used for

Levothyroxine contains levothyroxine sodium which is a synthetic form of the hormone thyroxine.

Thyroxine is normally in the body produced by the thyroid gland in the neck. It controls many bodily functions, mainly to do with growth and energy.

Levothyroxine is used to treat an under active thyroid which is not producing sufficient thyroxine.

2. Before you take Levothyroxine Tablets

DO NOT take Levothyroxine Tablets if:

- you know that you are allergic to levothyroxine sodium or any of the other ingredients of Levothyroxine (see section 6 of this leaflet)
- you have been told that your thyroid is overactive.

Please tell your doctor if any of the above applies to you.

Special care with Levothyroxine is required if you:

- suffer from diabetes. The dosage of your diabetic treatment may need to be altered
- suffer from high blood pressure, heart failure or a heart attack (your doctor may advise an ECG test if you have heart disease or are elderly)
- suffer from any condition which affects your adrenal glands (your doctor will be able to advise you as you may require additional treatment)
- are elderly
- have a long standing history of low thyroxine levels
- suffer from seizures (fits) as these may occur more frequently.

Even though some of the above may be obvious, it is important that your doctor is aware if any of them apply to you.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The effects of these medicines may change, especially if you are taking:

- medicines called cardiac glycosides (e.g. digoxin) used to treat heart conditions such as heart failure
- insulin and other treatments for diabetes
- colestyramine, colestipol or lovastatin which reduces the level of cholesterol (fat) in the blood
- calcium salts (used to treat low levels of calcium in your blood)
- rifampicin, used to treat infection
- iron preparations
- cimetidine, used to treat excess acid in the stomach
- beta-blockers (e.g. propranolol) used to treat high blood pressure
- anticonvulsants (e.g. phenytoin, carbamazepine, primidone) used to prevent fits
- anticoagulants (e.g. warfarin) used to thin the blood and treat blood clots
- tricyclic antidepressants (e.g. amitriptyline, imipramine) used to treat depression
- medicines containing hormones like oral contraceptives, androgens or corticosteroids
- medicines to relieve inflammation like phenylbutazone, acetylsalicylic acid
- medicines used to regulate your heart-rate
- Imatinib, used for the treatment of cancer
- Barbiturates, used to induce sleep or sedation
- medicines to regulate the salt levels in the body (e.g. Sodium Polystyrene Sulfonate)
- medicines to reduce swelling and mucous formation in the nose, throat and sinuses.
- sucralfate, used for the treatment of gut ulcers
- ketamine, used as an anaesthetic (if you are having an anaesthetic, ensure that the staff are aware that you are taking levothyroxine)
- medicines that stimulate the sympathetic nervous system such as adrenaline (ensure that the staff are aware that you are taking levothyroxine).

Pregnancy and breast feeding

If you are pregnant or planning to become pregnant or are breast-feeding discuss your medication with your doctor. The decision on whether it is best to take levothyroxine tablets during pregnancy or breast feeding will be made by your doctor.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Levothyroxine tablets should not interfere with your ability to drive or use machinery.

Important information about some of the ingredients of Levothyroxine Tablets

This medicine also contains lactose, a sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Levothyroxine Tablets

Always take Levothyroxine Tablets exactly as your doctor has told you. Do NOT take more than your doctor tells you to. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets with a glass of water, preferably before breakfast.

The usual starting dose for adults is 50 to 100 micrograms daily. This may be adjusted after a few weeks depending on the response to your treatment which will be monitored by blood tests.

For patients over 50 years the starting dose will not usually exceed 50 micrograms.

Children under 12 years:

The dose for children depends on their age, weight and the condition being treated.

Your child will be monitored to make sure he/she gets the right dose. Give your child this medicine at least half an hour before the first meal of the day.

Congenital hypothyroidism in infants:

Initially 10 to 15 micrograms/kg body weight a day for the first 3 months. The dose will then be adjusted depending on response to treatment.

Acquired hypothyroidism in children:

Initially 12.5 to 50 micrograms a day. The dose should be increased gradually every 2 to 4 weeks depending on response to treatment.

If required the tablets can be dissolved in 10 to 15ml of drinkable water and given freshly prepared with some more liquid (5 to 10ml).

In the event of stopping treatment, Levothyroxine tablets should be withdrawn gradually under the supervision of your doctor.

If you take more Levothyroxine Tablets than you should:

If you think that you, or any other person, have taken too many tablets, contact your doctor or hospital casualty department immediately. Remember to take the pack and any remaining tablets as well as this leaflet with you so that the medical staff know exactly what you have taken.

If you forget to take your Levothyroxine Tablets:

If you miss a dose but remember within two or three hours you can still take that dose. If you miss a dose for longer then do not catch up. Wait until your next dose is due and take the normal amount.

4. Possible side effects

Like all medicines, Levothyroxine tablets can sometimes cause side effects, although not everybody gets them.

The following effects can occur if your initial dose of medicine is too high.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

- fever
- intolerance to heat
- mild hair-loss is seen in children.
- loose stools
- shaking (tremor), restlessness, excitability
- difficulty in sleeping
- rapid heart beat or angina (pain in chest on exercise)
- fluid accumulation (oedema).

You should consult your doctor if any of the above effects occur. The effects usually go away when the dose has been changed.

Other side effects you could experience are:

- irregular heart beats, rapid heart beat, palpitations (thumping heart beats)
- muscle cramps or weakness
- vomiting
- headaches, flushing, sweating
- loss of weight
- menstrual irregularities
- seizures (fits) in patients with known history of epileps

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Levothyroxine Tablets

Keep this medicine out of the sight and reach of children.

Do not use Levothyroxine tablets after the expiry date which is stated on the box. The expiry date refers to the last day of that month. If your tablets are out of date, take them to your pharmacist who will get rid of them safely.

Do not store above 25°C. Store in the original package and protect from light.

6. Further information

This leaflet concerns two strengths of Levothyroxine tablets. Each strength contains respectively 50 and 100 micrograms of anhydrous levothyroxine sodium.

The tablets also contain sodium citrate, lactose, maize starch, acacia powder, magnesium stearate and purified water.

What Levothyroxine Tablets look like and contents of the pack

Each tablet is scored on one side and engraved on the other with either

50mcg – FW21

100mcg – FW31

They are packed in a blister pack of 28, 56 or 112 tablets and polypropylene containers of 28, 56, 100, 112, 500 or 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mercury Pharma (Generics) Ltd.,

No.1 Croydon, 12-16 Addiscombe Road, Croydon CR0 0XT, UK.

Manufacturer

Custom Pharmaceuticals Ltd.,

Tecore House, Conway Street, Hove, East Sussex, BN3 3LW, UK.