50 micrograms/5 ml and 100 micrograms/5 ml Oral Solution levothyroxine sodium

Levothyroxine 25 micrograms/5 ml,

Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

only. Do not pass it on to others. It may harm

them, even if their signs of illness are the

same as yours. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side

What is in this leaflet 1. What Levothyroxine is and what it is used for What you need to know before you take Levothyroxine

effects not listed in this leaflet. See section 4.

How to take Levothyroxine 4. Possible side effects How to store Levothyroxine

What Levothyroxine is and what it is

used for Levothyroxine Oral Solution contains levothyroxine which is used to treat hypothyroidism, a condition in which the thyroid

gland is underactive and so does not make

Levothyroxine is also used to treat thyroid

enough thyroxine for the body's needs.

Do not take Levothyroxine if you:

6. Contents of the pack and other information

cancer and diffuse non-toxic goitre or Hashimoto's thyroiditis, conditions in which the thyroid gland becomes enlarged causing a swelling in the front of the neck. What you need to know before you take Levothyroxine

have a heart attack (acute myocardial infarction), inflammation of the heart muscle (acute myocarditis) or inflammation of the sac surrounding the heart (acute pancarditis)

suffer from adrenal insufficiency and you do

not have adequate corticosteroid cover

are pregnant do not take this medicine in combination with other medicines to treat hyperthyroidism (see the section on Pregnancy and breast-feeding).

Warnings and precautions Talk to your doctor or pharmacist before taking Levothyroxine if you: have heart disease, problems with your

are suffering from an overactive thyroid gland (hyperthyroidism), an underactive adrenal

gland, diabetes, or have had an underactive thyroid gland for some time. Are about to undergo laboratory testing for

monitoring your thyroid hormone levels, you

must inform your doctor and/or the laboratory

circulation or high blood pressure

personnel that you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect results of your laboratory tests. Depending on the test, the results may be falsely high or falsely low

taking biotin before performing laboratory

tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin. This could affect the results of laboratory tests. Please inform your doctor and/or the laboratory

personnel, if you are taking such products (Please note the information in section Other

In low birth weight premature neonates, the

Please tell your doctor or pharmacist if you are

taking, have recently taken or might take any

other medicines. Levothyroxine can interfere

particular tell your doctor or pharmacist if you

phenytoin, phenobarbital, carbamazepine,

treatment (see section 4. "Possible side effects"). Hashimoto's thyroiditis.

doctor will monitor very carefully for heart

problems when starting Levothyroxine

Other medicines and Levothyroxine

medicines and Levothyroxine).

due to biotin. Your doctor may ask you to stop

with the action of some other drugs and some drugs can have an effect on levothyroxine. In

primidone)

drugs)

for stomach ulcer

supplements

medication for diabetes

Children

take the following drugs: medication to stop your blood clotting (for example warfarin) medication for depression (for example sertraline, imipramine, amitriptyline) medication for epilepsy (for example

tuberculosis) digoxin or amiodarone (for your heart) propranolol (for high blood pressure) lovastatin (for high cholesterol levels)

phenylbutazone or aspirin (anti-inflammatory

rifampicin (for infections, particularly

oestrogen, oestrogen containing products and oral contraceptives androgens or corticosteroids sucralfate, cimetidine or aluminium hydroxide

colestyramine or colesevelam to lower your cholesterol levels sodium polystyrene sulphonate (to lower your potassium levels) or calcium or iron

medicinal product). Levothyroxine can be taken with these

medicines but not at the same time: chloroquine or proguanil for the prevention of malaria protease inhibitors (for example ritonavir,

indinavir and lopinavir) used to treat HIV

sevelamer (used to treat high levels of

products containing St. John's Wort (a herbal

phosphate in the blood in patients with kidney failure) · tyrosine kinase inhibitors (for example

imatinib and sunitinib) used to treat cancer propylthiouracil (used to treat hyperthyroidism) sympathomimetic agents (medicines that work

by stimulating the sympathetic nervous system, such as adrenaline and phenylephrine) beta-sympatholytics (used to treat cardiac arrest and low blood pressure) glucocorticoids (steroid hormones used to treat adrenal insufficiency and other diseases) soy-containing products (these can decrease absorption of levothyroxine) other aluminium-containing drugs

enhance the visibility of vascular structures and organs during radiographic procedures) orlistat (medicine to treat obesity) biotin, you must inform your doctor and/or the laboratory personnel when you are about to undergo laboratory testing for monitoring your thyroid hormone levels. Biotin may affect

iodine containing contrast media (used to

taking Levothyroxine. If you go into hospital to have an operation, tell the anaesthetist or the medical staff that you are taking Levothyroxine. It may react with an

results of your laboratory tests (see warnings

Let your doctor or pharmacist know you are

anaesthetic (ketamine) which you may be given before an operation. Please tell your doctor if you are taking or have recently taken any other medicines, including

medicines obtained without a prescription.

Proton pump inhibitors (such as omeprazole,

reduce the absorption of levothyroxine from the intestine and thereby make it less effective. If

you are taking levothyroxine while receiving

treatment with proton pump inhibitors, your

esomeprazole, pantoprazole, rabeprazole and lanzoprazole) are used to reduce the amount of acid produced by the stomach, which may

Proton pump inhibitors:

and precautions).

are allergic to levothyroxine or any of the other doctor should monitor your thyroid function and ingredients of this medicine (listed in section 6) may have to adjust the dose of Levothyroxine. Levothyroxine with food, drink and alcohol Products that contain soy (namely soy supplements) may interact with levothyroxine, ask your doctor or pharmacist for advice. You should take your Levothyroxine on an

empty stomach, usually before breakfast. Pregnancy and breast-feeding Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant or breast-feeding, think you

may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are pregnant while taking this medicine your doctor will monitor you closely. **Driving and using machines** Your medicine is unlikely to affect your ability to drive or to operate machinery.

ingredients of Levothyroxine Levothyroxine contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed). Levothyroxine contains glycerol which may cause headache, stomach upset and diarrhoea. This medicine contains less than 1 mmol dium (23 mg) per 100 ml, that is to say

Always take this medicine exactly as your doctor

or pharmacist has told you. Check with your

Your doctor will have decided what dose you

If you are switching from the oral solution to the

tablet version of levothyroxine or from the tablet

version to the oral solution of levothyroxine

your doctor will monitor you more closely.

You should take your Levothyroxine on an

empty stomach, usually before breakfast.

doctor or pharmacist if you are not sure.

should take each day depending on your

Important information about some of the

How to take Levothyroxine

condition. Your doctor will take blood samples at regular intervals to monitor your response to treatment. The duration of treatment is usually for life if you are being treated for hypothyroidism, non-toxic diffuse goitre or

The usual daily dosages are:

Adults and children over 12 years:

essentially 'sodium-free'.

100 micrograms a day, increasing by 25 to 50 micrograms every 3-4 weeks, until you are taking the right amount for your condition. The usual maintenance dose is 100 to 200 micrograms daily.

For diffuse non toxic goitre or Hashimoto's

For hypothyroidism, the starting dose is 50 to

thyroiditis the recommended dose is 50-200 micrograms per day.

Administration

For the treatment of thyroid cancer the recommended dose is 150-300 micrograms per

day. Older patients (over 50 years of age) and

patients with severe hypothyroidism or heart disease: The starting dose is 12.5 micrograms a day,

increasing by 12.5 micrograms every 4 weeks until the correct dose is obtained. The usual final dose is between 50 and 200 micrograms daily. Children under 12 years: The dose for children depends on their age or

they get the right dose. Infants should be given this medicine in the morning, at least half an hour before the first meal of the day. For congenital hypothyroidism in infants, the

weight. They will be monitored to make sure

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

For acquired hypothyroidism in children, the initial dose is 12.5 to 50 micrograms a day. The dose should be increased gradually every 2 to 4 weeks depending on response to treatment.

Please use the oral syringe provided to deliver your specific dose – see instructions below. The syringe can be used to measure your dose by drawing the liquid to the correct mark on the syringe. For example, if your dose is 50 micrograms daily then the corresponding volume would be:

For the 25 microgram/5 ml strength – 2 x 5 ml

(10 ml in total)

For the 50 microgram/5 ml strength - 5 ml For the 100 microgram/5 ml strength – 2.5 ml

How to use the oral syringe:

- Shake the bottle well, making sure the cap is firmly on the bottle.
- Remove the cap. Note: Keep the cap nearby to close the bottle after each use.
- Push the plastic adapter into the neck of the bottle. Note: The adapter must always stay in the bottle.
- 4. Take the syringe and check the plunger is fully down.
- Keep the bottle upright and insert the oral syringe firmly into the plastic adapter.
- 6. Turn the whole bottle with the syringe upside down.
- Slowly pull the plunger down fully so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside the oral syringe.
- Then pull the plunger slowly back to the volume you need for your dose.
- Turn the whole bottle with the syringe the right way up and take the syringe out of the
- 10. The dose of medicine can now be swallowed directly from the oral syringe. Please ensure that you are sitting upright and the plunger must be pushed slowly to allow you to swallow the dose.
- 11. Replace the child resistant cap after use, leaving the adapter in place. 12. Cleaning: After use, wipe the outside of the
- syringe with a dry, clean tissue. If you take more Levothyroxine than you should

If you accidentally take an overdose of your medicine, either call your doctor straight away, or go to your nearest hospital casualty department. Symptoms of overdose include fever, irregular heartbeat, muscle cramps, headache, restlessness, flushing, sweating or diarrhoea. Always take any remaining medicine, the container and the label with you, so that the medicine can be identified. If you forget to take Levothyroxine

If you forget to take your medicine, take your

dose when you remember and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose. If you have forgotten several doses tell your doctor when you have your next check-up or blood test. It can be dangerous to stop taking your medicine without your doctor's advice. If you are worried, ask your doctor or pharmacist for advice.

If you stop taking Levothyroxine For your treatment to be successful, you must take Levothyroxine regularly at the dosage

prescribed by your doctor. Do not change, suspend or stop the prescribed treatment without talking to your doctor. Symptoms of disease may return if you suspend or stop treatment before you should. The nature of these symptoms depends on the underlying disease. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side

These usually only happen if the dose you are taking is too high. If any of the following happen, stop taking Levothyroxine and tell your doctor immediately

effects, although not everybody gets them.

or go to the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in

- swallowing or breathing, itchy rash (hives), fainting yellowing of the skin and eyes also called
- iaundice very high temperature, fast and irregular heartbeat, dizziness or fainting, fits and confusion, caused by high levels of thyroid

hormones (known as a "thyroid crisis").

These are all very serious side effects. If you have them, you may have a serious reaction to Levothyroxine. You may need urgent medical attention or hospitalisation. All of these very serious side effects are very rare. Tell your doctor if you notice any of the following:

Fast or irregular heartbeats, palpitations, chest pain, muscle cramps or weakness, headache, restlessness, excitability, flushing, sweating,

diarrhoea, vomiting, fever, menstruation problems, headaches and vision problems due to high blood pressure in the brain, tremor, sleeplessness, heat intolerance and excessive weight loss. Rash, itching and puffiness may also occur. If you feel unwell in any other way, tell your

doctor as soon as you can. Additional side effects in children

In premature newborn infants, severe heart

You may not have any of them.

problems can occur when starting treatment. Children may have some hair loss at the beginning of treatment, however this is usually temporary and the hair returns.

Do not be alarmed by this list of possible events.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRAYellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

How to store Levothyroxine

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

Expiry date

Dispose of any remaining medicine 2 months after opening.

Do not use after the expiry date which is stated on the label and carton after EXP (month, year). The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C.

Store in the original package in order to protect from light.

Do not use Levothyroxine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Contents of the pack and other information

What Levothyroxine contains

- The active substance is levothyroxine sodium. Each 5 ml of oral solution contains levothyroxine equivalent to levothyroxine sodium anhydrous 25 micrograms, 50 micrograms or 100 micrograms.
- It also contains the following inactive ingredients: glycerol (E422), citric acid monohydrate, sodium methyl parahydroxybenzoate (E219), sodium hydroxide and purified water.

What Levothyroxine looks like and contents of the pack

Levothyroxine is a clear colourless liquid. Each bottle contains 75 ml or 100 ml of levothyroxine oral solution. Levothyroxine is available in packs containing one or two glass bottles, each filled with 75 ml oral solution or one glass bottle filled with 100 ml oral solution. A 5 ml medication syringe is also included to help measure the dose.

Not all pack sizes may be marketed. **Marketing Authorisation Holder:**

Teva UK Limited, Ridings Point, Whistler Drive,

Castleford, WF10 5HX, United Kingdom

Manufacturer: Galenica Pharmaceutical Industry S.A., 3rd km

Old National Road Chalkida-Athens. Glifa Chalkida, Eubia, 34100, Greece This leaflet was last revised in February 2025.

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