

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:

1. Shake the bottle well, making sure the cap is firmly on the bottle.
2. Remove the cap. Note: Keep the cap nearby to close the bottle after each use.
3. 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.
5. Keep the bottle upright and insert the oral syringe firmly into the plastic adapter.
6. Turn the whole bottle with the syringe upside down.
7. 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.
8. Then pull the plunger slowly back to the volume you need for your dose.
9. Turn the whole bottle with the syringe the right way up and take the syringe out of the bottle.
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 effects, although not everybody gets them. 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 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 jaundice
- 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 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. You may not have any of them.

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 MHRA Yellow 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.

5 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.

6 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

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