Levothyroxine Oral Solution contains the active ingredient levothyroxine sodium. It is used to treat hypothyroidism, a condition in which the thyroid gland is underactive and so does not make enough thyroxine for the body's needs. Levothyroxine Oral Solution is also used to treat thyroid 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.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEVOthyroxine Oral Solution**

Do not take Levothyroxine Oral Solution:
- If you are allergic to levothyroxine or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from adrenal insufficiency and you do not have adequate corticosteroid cover.
- If you have a heart attack (acute myocardial infarction), inflammation of the heart muscle (acute myocarditis) or inflammation of the sac surrounding the heart (acute pericarditis).
- If you are pregnant do not take this medicine in the first trimester of your pregnancy.
- If you have a heart attack (acute myocardial infarction), inflammation of the heart muscle (acute myocarditis) or inflammation of the sac surrounding the heart (acute pericarditis).
- If you are allergic to levothyroxine or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from adrenal insufficiency and you do not have adequate corticosteroid cover.
- If you have a heart attack (acute myocardial infarction), inflammation of the heart muscle (acute myocarditis) or inflammation of the sac surrounding the heart (acute pericarditis).
- If you are pregnant do not take this medicine in the first trimester of your pregnancy.

Other medicines and Levothyroxine Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Levothyroxine can interfere with the action of some other drugs and some drugs can have an effect on Levothyroxine. In particular tell your doctor or pharmacist if you take the following drugs:
- Medication to stop your blood clotting (for example Warfarin).
- Medication for epilepsy (for example Phenytoin, Phenobarbital, Carbamazepine).
- Medication for diabetes.
- Rifampicin (for infections, particularly tuberculosis).
- Digoxin or Amodarone (for your heart).
- Propranolol (for high blood pressure), Lovastatin.
- Phenytoin or Carbamazepine (for example Phenytoin, Phenobarbital, Carbamazepine).
- Oestrogen, oestrogen containing products and oral contraceptives, androgens or corticosteroids.
- Sucralfate, Gimelidine or aluminium hydroxide for a stomach ulcer. Colestyramine to lower your cholesterol levels or calcium carbonate or iron supplements.
- Chloroquine or prog買う for the prevention of malaria.
- Protease inhibitors (for example ritonavir, indinavir and lopinavir) used to treat HIV.
- Sevelamer (used to treat high levels of phosphate in the blood in patients with renal failure).
- Tyrosine kinase inhibitors (for example imatinib and sunitinib) used to treat cancer.
- Propylthiouracil (used to treat hyperthyroidism).

**3. HOW TO TAKE LEVOthyroxine Oral Solution**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Levothyroxine Oral Solution should be swallowed.

Your doctor will have decided what dose you should take each day depending on your condition. Your doctor will take blood samples at regular intervals to monitor your response to treatment.

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.

**Administration**

You should take your Levothyroxine Oral Solution on an empty stomach, usually before breakfast.

**For hypothyroidism:**

Adults and children over 12 years:

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

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

**Older patients (over 50 years of age):**

The recommended starting dose is 12.5 micrograms a day, increasing by 12.5 micrograms every 2 weeks until the correct dose is obtained. The usual final dose is between 50 and 200 micrograms daily. This dose also applies to patients with severe hypothyroidism and to those with heart disease.

**Children under 12 years:**

The dose for children depends on their age or weight. They will be monitored to make sure they get the right dose. The following is a guide:
If you accidentally take an overdose of your medicine, ask your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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. (See details below) United Kingdom: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store Ireland: HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEVOTHYROXINE ORAL SOLUTION
Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package in order to protect from light. Dispose of any remaining medicine 8 weeks after opening.

Levothyroxine Oral Solution is odourless. Do not use this medicine if you notice that the solution has an odour. 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 Oral Solution contains
- The active substance is levotyroxine sodium. Each 5 ml of oral solution contains levotyroxine equivalent to levotyroxine sodium anhydrous 25micrograms, 50micrograms or 100micrograms.
- The other ingredients are glycerol, citric acid monohydrate, sodium methyl parahydroxybenzoate (E219), sodium hydroxide and purified water.

What Levothyroxine Oral Solution looks like and contents of the pack
Levothyroxine Oral Solution is a clear, colourless liquid. Each bottle contains 100ml of oral solution. A plastic dosing syringe (pipette) is also included to help measure the dose.

Marketing Authorisation Holder
Mercury Pharmaceuticals Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK
Manufacturer
FAMAR NETHERLANDS BV, Bladel Production Site, Industrieweg 1, 5531 AD BLADEL, The Netherlands
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If you feel unwell in any other way, tell your doctor as soon as you can. 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. (See details below)

United Kingdom: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
Ireland: HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.