

*This is an English translation of the German Patient Information Leaflet for L-Thyroxin ALIUD PHARMA GmbH which has been kindly supplied by a member. Thyroid UK cannot be held responsible for the accuracy of the information below.*

## **L-Thyroxin ALIUD PHARMA GmbH**

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

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### **1. What Levothyroxine tablets are and what they are used for**

Levothyroxine belongs to a group of medicines called thyroid hormones, which are used to treat hypothyroidism (underactive thyroid gland).

### **2. Before you take**

Do not take Levothyroxine tablets and tell your doctor if you:

- are allergic (hypersensitive) to anhydrous levothyroxine sodium or any other ingredients in Levothyroxine tablets (see section 6).
- are suffering from a condition that produces excessive quantities of thyroid hormone (thyrotoxicosis).
- are suffering from untreated adrenal problems.

Check with your doctor or pharmacist before taking Levothyroxine tablets if you:

- have any heart problems or have had a heart attack
- suffer from high blood pressure
- are elderly or have severe long term hypothyroidism (underactive thyroid gland)
- are suffering from a condition caused by an underactive adrenal gland such as panhypopituitarism
- have diabetes.

## **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. Especially:

- medicines to treat diabetes (eg insulin, metformin)
- medicines to control your heart rate such as digoxin
- tricyclic antidepressants (eg amitriptyline, doxepin)
- medicines that stimulate the sympathetic nervous system such as adrenaline (epinephrine)
- anticoagulants (used to thin the blood) such as warfarin, dicoumarol, acenocoumarol, phenindione
- sodium polystyrene sulphonate (used to treat kidney disease)
- colesytramine (used to treat diarrhoea)
- medicines to treat stomach ulcers such as sucralfate, cimetidine
- aluminium hydroxide (used to treat heartburn)
- medicines containing calcium carbonate
- "iron" tablets (containing ferrous sulphate)
- medicines to treat epilepsy such as carbamazepine, phenytoin, phenobarbital, primidone
- rifampicin (used to treat serious infections)
- aspirin and phenylbutazone (medicines to reduce inflammation)
- propranolol (a beta-blocker)
- medicines containing oestrogen (eg HRT, oral contraceptives – "the pill")
- amiodarone (used to treat some heart conditions)
- ketamine (an anaesthetic)
- lovastatin or colesvelam (used to reduce cholesterol)
- orlistat (used to aid weight loss)
- corticosteroids (eg hydrocortisone, prednisolone)
- medicines containing testosterone and mesterolone.

## **Pregnancy and breast-feeding**

If you are pregnant particularly in the first three months, planning to become pregnant or are breast-feeding tell your doctor or pharmacist before taking this medicine.

## **3 How to take**

Always take Levothyroxine tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Swallow the tablets with water, before food.

### **Doses:**

Adults:

Initially 50-100micrograms a day increased by 50micrograms every 3-4 weeks up to a maximum of 150-300micrograms a day, until normal metabolism is maintained.

Patients over 50 years:

Initially no more than 50micrograms a day should be taken.

Patients over 50 years with heart disease:

25micrograms a day or 50micrograms every other day should be taken, this may be increased by 25micrograms a day every 4 weeks.

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 15micrograms/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 50micrograms 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).

Juvenile myxoedema:

Initially 25micrograms a day, increased by 25micrograms every 2-4 weeks until mild toxic symptoms appear, the dose will then be reduced slightly. In children over 1 year, initially 2.5-5micrograms per kg of bodyweight a day should be taken. If you take more than you should If you (or someone else) swallow a lot of the tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include:

- Mild to moderate overdose: fever, angina, a racing heart, irregular heart beats, muscle cramps, headache, restlessness, flushing, sweating, diarrhoea.
- Severe overdose: thyroid crisis including irregular heart beats, heart failure, collapse, coma, death.

Signs and symptoms of increased thyroid hormone levels may not be seen for up to 5 days.

If you forget to take the tablets.

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking the tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

#### **4 Possible side effects**

Like all medicines, Levothyroxine tablets can cause side-effects, although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

Tell your doctor if you notice any of the following side effects:

- Allergic reactions: including a rash which may be itchy or swelling.

The following side effects may be due to high doses and usually disappear after reducing the dose or stopping the tablets. Tell your doctor if you notice:

- Heart: a racing heart, irregular heart beats, palpitations, anginal pain.
- Central nervous system: headache, restlessness, excitability, difficulty in sleeping, flushing, sweating, fever, involuntary shakiness, heat intolerance.
- Stomach and intestines: diarrhoea, being sick, excessive weight loss.
- Muscle and bone: muscle cramps, muscular weakness.
- Other: partial hair loss during first few months of therapy.

#### **5 How to store**

- Keep out of the reach and sight of children.
- Do not store above 25°C. Store in the original package. Keep container in the outer carton.
- Do not use Levothyroxine tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
- Unwanted medicines should not be disposed responsibly and appropriately

#### **6 Further information**

What Levothyroxine tablets contain

- The active substance (the ingredient that makes the tablets work) is anhydrous levothyroxine sodium. Each tablet contains either 50micrograms or 100micrograms of the active substance.
- The other ingredients are, magnesium stearate, maize (corn) starch, stearic acid and pregelatinised maize starch.

This leaflet was last revised in November 2013.