Levothyroxine 50 and 100 micrograms Tablets
Liothyronine Sodium

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, pharmacist or nurse.

Your medicine is either Levothyroxine 50 micrograms or 100 micrograms tablets depending on what your doctor has prescribed. It will be known as Levothyroxine Tablets for ease reading.

What is in this leaflet
1. What Levothyroxine Tablets are and what they are used for
2. What you need to know before you take Levothyroxine Tablets
3. How to take Levothyroxine Tablets
4. Possible side effects
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6. Further information and contents of the pack

1. WHAT LEVOTHYROXINE TABLETS ARE AND WHAT THEY ARE USED FOR

Levothyroxine is a hormone that is produced naturally in the body by the thyroid gland. Levothyroxine is a synthetic version of this hormone. Thyroxine controls how much energy your body uses. When the thyroid gland does not produce enough thyroxine (a condition known as hypothyroidism), the body's functions slow down. Some of the most common symptoms of hypothyroidism are:

- tiredness
- weight gain despite dieting
- feeling depressed

Levothyroxine Tablets are used to replace the thyroxine that your thyroid gland cannot produce and prevent the symptoms of hypothyroidism. Before starting your treatment your doctor will want you to carry out a blood test to work out how much levothyroxine you need.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEVOTHYROXINE TABLETS

Do not take Levothyroxine Tablets:

- if you have an underactive thyroid gland that produces too much thyroid hormone (hyperthyroidism).
- if you have overactive thyroid gland that affects your adrenal glands (your doctor will be able to advise you if you are not sure). if you have any of the conditions in 1. above, you do not take this medicine and go back to your doctor to discuss your treatment.

Wear the wrong Tablet?

Talk to your doctor, pharmacist or nurse before taking Levothyroxine Tablets.

- if you have received the wrong tablet or any of the other ingredients of this medicine (listed in section 6).
- if you have a viral or bacterial infection, it may affect your treatment and your doctor will decide whether you need to continue treatment with levothyroxine whilst you are pregnant, particularly in the first three months of your pregnancy.

Driving and using machines:

The medicine should not affect your ability to drive or use machines.

Levothyroxine Tablets contain lactose. This medicine also contains trolley sodium (sodium citrate). If you have been told by your doctor that you have intolerance to some of these ingredients, contact your doctor before taking the medicine.

3. HOW TO TAKE LEVOTHYROXINE TABLETS

Always take the medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You may be taking this medicine for many years. Your doctor will be able to advise you if you are not sure.

Your dose will be decided by your doctor and will depend on the results of your blood tests. The dose you should take will be on the label attached by your pharmacist. Swallow the tablets whole with a little water before or after your first meal of the day.

Adulthood:

The recommended starting dose is 50 - 100 micrograms every day. Your doctor may increase the dose you take every 3-4 weeks up to 200 micrograms daily. The final daily dose may be up to 200-400 micrograms daily.

Pregnancy:

The recommended starting dose will be no more than 50 micrograms every day. The dose may be increased by 25 micrograms every 3-4 weeks up to 150 micrograms daily. You should not exceed 200 micrograms daily.

In children and adolescents:

For very young children, your doctor is likely to prescribe Levothyroxine Oral Solution instead of tablets.

Congenital hypothyroidism in infants:

This is a condition where your baby has been born with a thyroid gland that does not produce enough thyroxine. The starting dose is 15-25 micrograms/kg body weight per day for the first month. The dose will then be added on depending on how your baby responds to the treatment.

Acquired hypothyroidism in children:

This is a condition where your child's thyroid gland stops working properly because it has been affected by another illness, e.g. in children with autoimmune disease or following a viral infection. The starting dose is 12.5 - 20 micrograms per day. The dose will then be increased by 25 micrograms every 2-3 weeks until your child is producing enough thyroxine. Your final daily dose will usually be between 50-200 micrograms daily.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, which may become apparent during treatment. Stop taking the tablets and go to hospital at once if you have:

- a rare allergic reaction such as swelling of the face, angina, or breathing is made easier by EVAS and household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

5. HOW TO STORE LEVOTHYROXINE TABLETS

Keep this medicine out of the sight and reach of children. Do not take this medicine after the expiry date which is stated on the 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 and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any other side effects not listed.

Not known (frequency cannot be estimated from the available data):

- headache
- flushing
- high temperature, sweating
- weight loss
- tremor, weakness, excitability, difficulty sleeping (insomnia)
- increased pressure around the brain in children that is not caused by a tumour or other diseases (benign intracranial hypertension)
- chest pain (angina), pounding, irregular or fast heartbeat
- diarrhoea, vomiting
- muscle cramps, muscle weakness
- deformity of the skull in infants caused by the early closure of joints in the skull bone (craniostenosis)
- growth in children, slow or stop due to changes in bone growth
- irregular periods
- intolerance to heat
- temporary hair loss in children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any other side effects not listed. Your pharmacist will be able to advise you if you are not sure. You may be taking this medicine for many years. Your doctor will be able to advise you if you are not sure.

Levothyroxine Tablets contain:

- the active substance is anhydrous levothyroxine sodium.
- the other ingredients are sodium citrate, lactose, maize starch, magnesium powder and magnesium stearate.

Levothyroxine Tablets look like and contents of the pack

Each tablet is engraved on one side with LT and engraved on the other with.

50mcg - 50 100mcg - 100

They are in a blister pack of 28, 56 or 112 tablets and polystyrene packaging of 28, 56, 112 or 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorization Holder

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Manufactured

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This leaflet was last revised in May 2018.