

Package leaflet: Information for the user

Liothyronine Sodium 20 micrograms Tablets

liothyronine sodium

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.

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 same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Liothyronine Sodium Tablets are and what they are used for
2. What you need to know before you take Liothyronine Sodium Tablets
3. How to take Liothyronine Sodium Tablets
4. Possible side effects
5. How to store Liothyronine Sodium Tablets
6. Contents of the pack and other information

1. What Liothyronine Sodium Tablets are and what are they used for

Liothyronine Sodium Tablets are a form of thyroxine which is quick acting and long lasting. Thyroxine is a hormone produced by the thyroid gland in the neck which controls many body functions.

Liothyronine Sodium Tablets are used to:

- treat some of the more severe conditions in which the thyroid does not produce enough thyroxine.
- balance the effect of medicines used to treat an overactive thyroid.

2. What you need to know before you take Liothyronine Sodium Tablets

Do not take Liothyronine Sodium Tablets:

- if you are allergic to liothyronine sodium or any of the other ingredients of this medicine (listed in Section 6)
 - if you have angina (chest pain when exercising) or conditions affecting your heart or circulation
 - if you are suffering from thyrotoxicosis (condition due to over activity of the thyroid gland)
- Speak to your doctor before you take this medicine if any of the above applies to you.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Liothyronine sodium tablets if:

- You are suffering from diabetes. Liothyronine Sodium Tablets may raise blood sugar levels
- You are suffering from a condition called myxoedema (which can happen when you have a problem with your thyroid gland) which makes your skin look swollen and dry
- You are elderly

- You have suffered from low levels of thyroid hormone in your body for a long time, as this may affect how your adrenal glands work. You may be given additional medication (corticosteroids) if this is the case
- You are suffering from any heart problems
- You are having increased blood pressure
- You suffer from increased heart rate sleeplessness, loose watery stools (suggesting increased metabolism) on initiation of treatment, dose reduction would be required
- You are initiating treatment, as an ECG test done at the time would be valuable
- If you are pregnant or breast feeding.

Speak to your doctor before you take this medicine if any of the above applies to you.

Other medicines and Liothyronine Sodium tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Liothyronine Sodium Tablets may affect or be affected by the following medicines:

- Anticoagulants (e.g. warfarin) used to thin the blood and prevent blood clots
- Anticonvulsants (e.g. carbamazepine or phenytoin) used to prevent fits
- Insulin and other treatments for diabetes
- Medicines called cardiac glycosides (e.g. digoxin) used to treat heart conditions such as heart failure
- Tricyclic antidepressants (e.g. amitriptyline/imipramine) used to treat depression
- Colestyramine/colestipol which reduces the level of cholesterol (fats) in the blood
- Oral contraceptives ('the pill')
- Amiodarone, used to treat irregular heart beats
- Barbiturates, used to induce sleep and decrease anxiety
- Primidone, used for seizures or fits.

Pregnancy and breast feeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The decision on whether it is best to take Liothyronine Sodium Tablets during pregnancy or breast feeding will be made by your doctor. Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Liothyronine Tablets should not interfere with your ability to drive or use machinery.

Liothyronine Sodium Tablets contains lactose

This medicine contains lactose, which is a sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Liothyronine Sodium Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Liothyronine Sodium Tablets are taken by mouth. They should be swallowed with a glass of water.

- If you have been prescribed a dose lower than 20 micrograms, you should allow a tablet to dissolve/disperse in 20 mL of water for 10 minutes, in a small measuring cup.
- You should gently swirl the solution occasionally to aid the dissolution/dispersion.
- You should then swirl the solution for a few seconds prior to using a suitable oral syringe to withdraw the amount of liquid corresponding to the dose prescribed (5mL for a 5mcg dose; 10 mL for a 10mcg dose) and squirt the liquid directly into your mouth by gently pressing the plunger.
- Any remaining liquid should be discarded.

Adults:

The dose will depend upon your condition, ranging from 10 micrograms to 60 micrograms daily in divided doses.

Children and elderly:

The dose may be started at 5 micrograms a day.

Please note that your doctor will monitor your thyroid function regularly to make sure that you are given the right dose for your condition.

The score line is not intended for breaking the tablet.

If you take more Liothyronine Sodium Tablets than you should:

This may cause agitation, confusion, headache, sweating and a rapid pulse. If you take too many tablets contact your doctor or nearest hospital casualty department as soon as possible. Take any remaining tablets and this leaflet with you so the medical staff will know what you have taken.

If you forget to take your Liothyronine Sodium Tablets:

Take the next dose at the correct time and then go on as before. It is important, in order for your medicine to work, that doses are not forgotten.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Liothyronine Sodium Tablets:

Do not stop taking Liothyronine Sodium Tablets unless your doctor tells you to.

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.

Seek urgent medical advice if you experience the following side effects:

- Allergic reactions such as rash, itching, oedema (abnormal accumulation of body fluid)
- Angina pain (pain in the chest when exercising), irregular, thumping or fast heart beats. Seek urgent advice from your doctor if you experience these heart-related symptoms. This may be a sign that your dose of liothyronine needs to be reduced. You must not stop or reduce the amount of liothyronine medicine you are taking without consulting with your doctor first.

Other side effects you could experience are:

Not known: frequency cannot be estimated from the available data

- Vomiting (being sick)
- Insomnia (sleeplessness)
- Fever
- Intolerance to heat
- Tremor (involuntary, rhythmic muscle movements)
- Muscle cramps or weakness
- Diarrhoea
- Restlessness or excitability
- Headache, face and neck redness, sweating
- Loss of weight.

Additional side effects in children

Not known: frequency cannot be estimated from the available data

Temporary loss of hair in children

These effects normally mean the dose of the medicine needs changing. You should consult your doctor if they occur. The effects usually go away when the dose has been changed.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Liothyronine Sodium Tablets

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

Do not use Liothyronine Sodium Tablets after the expiry date which is stated on the bottle after EXP.

The expiry date refers to the last day of that month.

Do not use your tablets if you notice that the container or the tablets are damaged.

Do not store above 25°C. Store in the original container in order to protect from light.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Remember:

This medicine is for you. Only a doctor can prescribe it for you. Never give this medicine to someone else; it could harm them, even if their symptoms seem the same as yours.

6. Contents of the pack and other information

What Liothyronine Sodium Tablets contain:

The active substance is liothyronine sodium 20 micrograms.

The other ingredients are lactose, maize starch, powdered acacia, sodium chloride, magnesium stearate, industrial methylated spirit, and purified water.

What Liothyronine Sodium Tablets look like and contents of the pack:

White uncoated tablets engraved on one side “GS 058” and with a breakline on the other. Liothyronine Sodium Tablets are supplied in container packs of 28 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mercury Pharma Group Ltd.,
Capital House,
85 King William Street,
London EC4N 7BL, UK

Manufacturer:

Custom Pharmaceuticals Ltd. Conway
Street, Hove, East Sussex, BN3 3LW

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