

Package leaflet: Information for the user

Liothyronine Sodium 20 micrograms Powder for Solution for Injection liothyronine sodium

Read all of this leaflet carefully before you are given 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.

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 injection is and what it is used for
2. What you need to know before you are given Liothyronine Sodium injection
3. How Liothyronine Sodium injection is given to you
4. Possible side effects
5. How to store Liothyronine Sodium injection
6. Contents of the pack and other information

1. What Liothyronine Sodium injection is and what it is used for

Liothyronine Sodium injection contains Liothyronine Sodium which is a quick acting, naturally occurring form of the hormone thyroxine.

Thyroxine is normally produced by the thyroid gland in the neck.

It controls many bodily functions, mainly to do with growth and energy.

Liothyronine Sodium injection is used to treat severe under activity of the thyroid gland (myxoedema) when it is not possible to give thyroid treatment by mouth. It may be used with other medicines such as steroids.

2. What you need to know before you are given Liothyronine Sodium injection

You should not be given Liothyronine Sodium injection:

- if you are allergic to liothyronine sodium or any of the other ingredients of this medicine (listed in section 6)
- if you have a disease involving the heart or blood vessels
- if you have pain in the chest (angina pectoris)
- if you have an overactive thyroid gland with raised levels of thyroid hormones (thyrotoxicosis).

Please tell your doctor before you are given this injection if any of the above applies to you.

Warnings and Precautions

Talk to your doctor or pharmacist before you are given Liothyronine Sodium injection if you:

- suffer from diabetes. The dosage of your diabetic treatment may need to be altered
- 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
- have heart failure (e.g. suggested by symptoms like swelling of the ankles, breathlessness etc.) or have high blood pressure

- are an elderly patient with history of hypothyroidism (low levels of thyroid hormones)
- suffer from disorders of the adrenal gland.

Other medicines and Liothyronine Sodium injection:

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

The effects of these medicines may change, especially if you are taking:

- medicines called cardiac glycosides (e.g. digoxin) used to treat heart conditions such as heart failure
- insulin and other treatments for diabetes
- anticonvulsants (e.g. phenytoin, carbamazepine, primidone) used to prevent fits
- anticoagulants (e.g. warfarin, phenindione) used to thin the blood and treat blood clots
- tricyclic antidepressants (e.g. sertraline) used to treat depression
- barbiturates (e.g. amobarbital) taken to induce sleep
- Antihypertensives (propranolol)
- Adrenaline (used to increase heart rate)
- Amiodarone (medication used for irregular heart beat)
- Rifampicin (treatment of tuberculosis).

Pregnancy and breast feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have baby, ask your doctor or pharmacist for advice before taking this medicine. The decision on whether it is in your best interests to have Liothyronine Sodium injection 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 Sodium injection should not interfere with your ability to drive or use machinery.

Liothyronine Sodium injection contains Dextran 110

This medicine also contains Dextran 110 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 medicinal product contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. How Liothyronine Sodium injection is given to you

This medicine will be diluted with sterile water before it is given to you. It will be injected slowly into a vein by a nurse or doctor.

The usual dose for adults is 5 to 20 micrograms. This may be repeated after 12 hours or less if required. The minimum interval between doses is four hours.

If you are given more Liothyronine Sodium injection than you should:

As the injection will be administered under the supervision of a doctor or nurse, it is unlikely that you will be given more than is necessary. However, if you have any concerns about the dose of your medicine discuss them with your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects you could experience are:

- Difficulty in breathing, rash, itching or swelling of the eyelids, face or lips. If you notice any of the above effects, speak to your doctor or nurse immediately as these can be signs of an allergic reaction.
- Irregular or rapid heartbeats, angina (pain in the chest on exercise) and palpitations (thumping heart beats). You should speak to your doctor or nurse immediately if any of these effects occur.

Other side effects:

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

- Muscle cramps or weakness
- Vomiting, diarrhoea
- Menstrual irregularities (experienced when thyroid hormones used for maintenance)
- Restlessness, excitability, trembling
- Headaches, flushing, sweating, fever
- Loss of weight
- Difficulty in sleeping

Additional side effects in children:

Rare (may affect up to 1 in 1,000 people)

- Benign intracranial hypertension in children (neurological disorder characterized by headache, nausea, vomiting)

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

- Intolerance to heat and Transient hair loss in children (when thyroid hormones used for maintenance)
- Craniostenosis (Developmental abnormality of the skull bone in children)
- Premature closure of epiphysis in children (Bone deformities)

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 Liothyronine Sodium injection

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 carton and label after EXP.

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

This information is primarily for healthcare professionals.

Do not store above 25°C. Store in the outer carton and protect from light. Reconstituted solution should be discarded after use.

6. Contents of the pack and other information

The active substance is Liothyronine Sodium 20 micrograms.

The other excipients are Dextran 110 freeze dried, sodium hydroxide and water for injection.

What Liothyronine Sodium injection looks like and contents of the pack

This medicine is packed as a freeze-dried white plug in a neutral glass vial for reconstitution with 1 or 2 ml of water for injection.

It is available as 5 vials in a carton pack.

Marketing Authorisation Holder and Company Responsible for Manufacture:

Mercury Pharmaceuticals Ltd., Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

This leaflet was last revised in October 2023