

Package Leaflet: Information for the user
Triiodothyronine 20 Micrograms Powder For
Solution For Injection
Liothyronine sodium

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU HAVE THIS MEDICINE.

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

1. WHAT TRIIODOTHYRONINE INJECTION IS AND WHAT IT IS USED FOR

Triiodothyronine 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.

Triiodothyronine injection is used to treat severe underactivity of the thyroid gland (myxoedema coma) 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 TRIIODOTHYRONINE INJECTION

Do not take Triiodothyronine injection if:

- you know that you are allergic to liothyronine sodium or any of the other ingredients of Triiodothyronine injection (see section 6 of this leaflet)
- you have a disease involving the heart or blood vessels.
- you have pain in the chest (angina pectoris)
- 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 taking Triiodothyronine injection if you:

- suffer from diabetes. The dosage of your diabetic treatment may need to be altered
- have heart failure (e.g. suggested by symptoms like swelling of the ankles, breathlessness etc.) or have high blood pressure
- are an elderly patient
- suffer from prolonged hypothyroidism (low levels of thyroid hormones)

- suffer from disorders of the adrenal gland.

Other medicines and Triiodothyronine injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 (Epinephrine) used to treat allergic reactions
- Norepinephrine used to increase blood pressure
- Amiodarone (medication used for irregular heart beat)
- Rifampicin (treatment of tuberculosis).
- Ketamine (used for anesthesia)

Pregnancy and breast feeding

If you are pregnant or breast-feeding, 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 in your best interests to have Triiodothyronine 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

Triiodothyronine injection should not interfere with your ability to drive or use machinery.

Triiodothyronine injection contains:

Triiodothyronine Injection contains less than 1mmol sodium (23mg) per dose, i.e. is essentially 'sodium-free'.

3. HOW TRIIODOTHYRONINE INJECTION IS GIVEN

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 recommended 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 take more Triiodothyronine 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, Triiodothyronine injection can cause side effects, although not everybody gets them.

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.

Other side effects:

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):

- Irregular or rapid heartbeats, angina (pain in the chest on exercise) and palpitations (thumping heart beats)
- Muscle cramps or weakness
- Vomiting, diarrhoea
- 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)
- Menstrual irregularities (experienced when thyroid hormones used for maintenance)
- Restlessness, excitability, trembling
- Headaches, flushing, sweating, fever
- Loss of weight
- Difficulty in sleeping

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

This information is primarily for healthcare professionals.

Do not store above 25°C. Keep the vials in the outer carton in order to protect from light.

Reconstituted product should be used immediately, and any unused portion should be discarded. For single use only.

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 Triiodothyronine injection contains

Triiodothyronine injection contains the active ingredient liothyronine sodium 20 micrograms. The other ingredients are Dextran 110 freeze-dried and sodium hydroxide

What Triiodothyronine 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.

Product Licence Holder and Company Responsible for

Manufacture:

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

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