

Package leaflet: Information for the user

Liothyronine sodium 5 micrograms, 10 micrograms, 20 micrograms Hard Capsules

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

The name of your product is Liothyronine sodium 5 micrograms, 10 micrograms or 20 micrograms Hard Capsules, but it will be referred to as Liothyronine sodium Capsules throughout this leaflet.

What is in this leaflet

- What Liothyronine sodium Capsules are and what they are used for
- What you need to know before you use Liothyronine sodium Capsules
- How to use Liothyronine sodium Capsules
- Possible side effects
- How to store Liothyronine sodium Capsules
- Contents of the pack and other information

1. What Liothyronine sodium Capsules are and what they are used for

The active substance of Liothyronine sodium Capsules is liothyronine sodium.

Liothyronine sodium Capsules 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 Capsules 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 Capsules

Do not take Liothyronine sodium Capsules if you:

- know that you are allergic to liothyronine sodium or any of the other ingredients (listed in section 6 at the end of this leaflet)
- have angina (chest pain when exercising) or conditions affecting your heart or circulation
- 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 Capsules if you:

- are suffering from diabetes. Liothyronine sodium Capsules may raise blood sugar levels
- 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
- are elderly (65 years or over)
- 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

- are suffering from any heart problems
- have increased blood pressure
- suffer from increased heart rate, sleeplessness, loose watery stools (suggesting increased metabolism) on initiation of treatment, a dose reduction would be required
- are starting treatment, as an ECG test (a recording of the electrical activity of your heart) will be valuable
- 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 Capsules:

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

Liothyronine sodium Capsules 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 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 best to take Liothyronine sodium Capsules during pregnancy or breast feeding will be made by your doctor. Ask your doctor or pharmacist for advice before taking any medicines.

Liothyronine sodium Capsules contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per each 5 micrograms, 10 micrograms or 20 micrograms hard capsule, that is to say essentially 'sodium-free'.

3. How to take Liothyronine sodium Capsules

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 Capsules are taken by mouth. They should be swallowed with a glass of water.

If you have difficulty swallowing a whole capsule, empty the contents of a capsule into a minimum of 20 ml of water. Stir and drink the whole liquid to ensure you take the full dose. It is possible to do this with Liothyronine because this substance is soluble in water.

If you have been prescribed a dose lower than 20 micrograms, Liothyronine sodium 5 micrograms Capsules and Liothyronine sodium 10 micrograms Capsules are also available.

Adults:

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

Use in 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.

If you take more Liothyronine sodium Capsules 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 Liothyronine sodium Capsules

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 dose.

If you stop taking Liothyronine sodium Capsules

Do not stop taking Liothyronine sodium Capsules 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.

Side effects you could experience are:

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

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.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Capsules

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

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

Do not store above 25°C.

Keep the blister in the outer carton in order to protect from light.

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 Liothyronine sodium Capsules contain

Liothyronine sodium 5 micrograms Capsules

- Each capsule contains 5 micrograms of the active substance liothyronine sodium.
- The other ingredients are: maize starch, magnesium stearate (E572).
- Liothyronine sodium 5 micrograms capsule shell contains: gelatin.

Liothyronine sodium 10 micrograms Capsules

- Each capsule contains 10 micrograms of the active substance liothyronine sodium.
- The other ingredients are: maize starch, magnesium stearate (E572).
- Liothyronine sodium 10 micrograms capsule shell contains: gelatin and titanium dioxide (E171).

Liothyronine sodium 20 micrograms Capsules

- Each capsule contains 20 micrograms of the active substance liothyronine sodium.
- The other ingredients are: maize starch, magnesium stearate (E572).
- Liothyronine sodium 20 micrograms capsule shell contains: gelatin, titanium dioxide (E171) and yellow iron oxide (E172).

What Liothyronine sodium Capsules look like and contents of the pack

Liothyronine sodium 5 micrograms Capsules are size 4, natural transparent, hard gelatin capsules.

Liothyronine sodium 10 micrograms Capsules are size 4, opaque white, hard gelatin capsules.

Liothyronine sodium 20 micrograms Capsules are size 4, opaque ivory, hard gelatin capsules.

They are packed in opaque PVC/PVDC/aluminium blisters. Each blister contains 7 or 10 capsules.

Pack sizes: 28, 56, 100, 112 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

ROMA Pharmaceuticals Limited
Gibraltar House,
Crown Square
Centrum 100,
Burton-upon-Trent
DE14 2WE

Manufacturer

GALENICA PHARMACEUTICAL INDUSTRY S.A.
3rd km Old National Road Chalkida-Athens,
Gifa Chalkida Eubia, 34100, Greece

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Roma
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