

Package leaflet: Information for the user **Liothyronine Sodium 5 microgram Tablets Liothyronine Sodium 10 microgram Tablets Liothyronine Sodium 20 microgram 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 the 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

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

Liothyronine Sodium Tablets are a form of thyroxine which is quick acting and long

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 (listed in Section 6 at the end of this leaflet)
- 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 (corticosteriods) if this is the case
- you are suffering from any heart problems • you have 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 starting treatment, as an ECG test (a recording of the electrical activity of your heart) will be valuable
- If you are pregnant or breast-feeding.
- If you are about to undergo laboratory testing for monitoring your thyroid hormone levels, you must inform your doctor and/or the laboratory personnel that you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect results of your laboratory tests. Depending on the test, the results may be falsely high or falsely low due to biotin. Your doctor may ask you to stop taking biotin before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair. skin, and nails could also contain biotin. This could affect the results of laboratory tests. Please inform your doctor and/ or the laboratory personnel, if you are taking such products (see section Other medicines and liothyronine sodium

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. If you are taking or have recently taken biotin, you must inform your doctor and/ or the laboratory personnel when you are about to undergo laboratory testing for monitoring your thyroid hormone levels. Biotin may affect results of your laboratory tests (see section Warnings and precautions).

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 Tablets during pregnancy or breast-feeding will be made by your doctor.

Driving and using machines

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

Information on sodium content

This medicine contains less than 1 mmol sodium (23mg) per dose, i.e. is essentially

3. How to take Liothyronine Sodium Tablets Always take 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.

For patients who have difficulty in swallowing a whole tablet, such as the elderly and young children, a whole tablet may be crushed and allowed to dissolve/disperse in a minimum of 20 mL of water. The entire volume of liquid should be consumed to ensure ingestion of the full dose.

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

Children and elderly:

The dose may be started at 5 microgram 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 **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. Side effects you could experience are:

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

- Vomiting (being sick) • Insomnia (sleeplessness)
- Intolerance to heat
- Tremor (involuntary, rhythmic muscle movements)
- Allergic reactions such as rash, itching, oedema (abnormal accumulation of body · Angina pain (pain in the chest when
- exercising)
- Irregular, thumping or fast heart beats Muscle cramps or weakness
- Restlessness or excitability
- · Headache, face and neck redness, sweating
- Loss of weight
- Additional side effects seen in children

· 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, 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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store Liothyronine Tablets Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the carton or blister and 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 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

6. Contents of the pack and other information

What Liothyronine Sodium Tablets contains

- The active substance is liothyronine sodium. Each tablet contains 5 microgram, 10 microgram or 20 microgram of liothyronine sodium
- The other ingredients are mannitol, maize starch, gum arabic powder (Acacia), sodium hydroxide and magnesium

What Liothyronine Sodium Tablets looks like and contents of the pack

Liothyronine Sodium 5 microgram Tablets are round, white to off-white-colored tablets, debossed with '5' on one side of the tablet and plain on the other side.

Liothyronine Sodium 10 microgram Tablets are round, white to off-white-colored tablets, debossed with '10' on one side of the tablet and plain on the other side. Liothyronine Sodium 20 microgram Tablets

are round, white to off-white-colored tablets, debossed with '20' on one side of the tablet and plain on the other side.

Liothyronine Sodium 5, 10 and 20 microgram Tablets are available in blister pack of 14, 28, 56, 112 tablets and bottle pack of 100 tablets. Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd. Unit 4, The Metro Centre, Dwight Road, Watford, WD18 9SS United Kingdom

This leaflet was last revised in 03/2025.



NON PRINTING COLOUR

CMO - ARTWORK DETAIL LABEL

| | | MFG. LOCATION | ACME GENERICS PVT. LTD. | | |
|--|---|---------------|-------------------------|-----------------|-----|
| PRODUCT | Liothyronine Sodium 5, 10 & 20 micrograms Tablets | | | | |
| BUYER/COUNTRY | SPUK | COMPONENT | Pack insert | | |
| DIMENSION | 140 x 280 mm | | PACK - | | |
| NEW ITEM CODE | 1051469 | OLD ITEM CODE | 1051124 | | |
| COLOUR SHADES | BLACK | | No. of Colours 1 | | |
| Change Control No. PC-CM1/2024/073 - Record No.: 440966 & PC-CM1/2025/005 - Record No.: 453196 | | | | Artwork Version | 3.0 |
| Design/Style | As per CMO Specification | | | | |
| Substrate | As per CMO Specification | | | | |
| Special Instructions | Printing clarity should be clear and sharp. | | | | |
| Autocartonator Requirements | NA | | | | |

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform SCM / PD for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM SCM / PD.