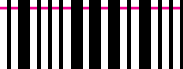


10471



Package leaflet: Information for the user
Liothyronine Sodium 5 micrograms Tablets
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 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

1. 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 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 is and what it is 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 (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 (corticosteroids) 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.

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 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 machinery.

Information on sodium content

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

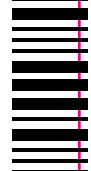
3. How to take Liothyronine Sodium Tablets

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.

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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.

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)
- Fever
- Intolerance to heat
- Tremor (involuntary, rhythmic muscle movements)
- 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
- Diarrhea
- 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 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.

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 protect the environment.

6. Contents of the pack and other information

What Liothyronine Sodium Tablets contains

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

What Liothyronine Sodium Tablets looks like and contents of the pack

Liothyronine Sodium 5 micrograms 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 20 micrograms 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 and 20 micrograms 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 03/2023.

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140 x 280 mm

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NON PRINTING COLOURS

CMO - ARTWORK DETAIL LABEL

		MFG. LOCATION	ACME GENERICS PVT. LTD.	
PRODUCT	Liothyronine Sodium 5 & 20 micrograms Tablets			
BUYER/COUNTRY	SPUK	COMPONENT	Pack insert	
DIMENSION	140 x 280 mm		PACK	-
NEW ITEM CODE	1048888	OLD ITEM CODE	NA	
COLOUR SHADES	BLACK		No. of Colours	1
Change Control No.	PC-CM1/2023/011 - Record No.: 382449		Artwork Version	1.0
Design/Style	As per CMO Specification			
Substrate	As per CMO Specification			
Special Instructions	Printing clarity should be clear and sharp.			
Autocart onator 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.				

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