1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

TERTROXIN 20 µg tablets

Liothyronine sodium

Contains sugar: Lactose 48,5 mg

Read all of this leaflet carefully before you start taking TERTROXIN 20 µg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TERTROXIN 20 µg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TERTROXIN 20 µg is and what it is used for
2. What you need to know before you take TERTROXIN 20 µg
3. How to take TERTROXIN 20 µg
4. Possible side effects
5. How to store TERTROXIN 20 µg
6. Contents of the pack and other information

1. What TERTROXIN 20 µg is and what it is used for

TERTROXIN 20 µg belongs to a group of medicines called thyroid preparations.

TERTROXIN 20 µg is 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.

TERTROXIN 20 µg is used in the treatment of:

- Coma due to myxoedema (severe hypothyroidism where you produce very low levels of thyroid hormones),
- Management of severe chronic thyroid deficiency,
- Hypothyroid states arising in treatment of thyrotoxicosis (an overactive thyroid gland that produces too much thyroid hormones),
- In thyrotoxicosis as additional treatment to carbimazole.

2. What you need to know before you take TERTROXIN 20 µg

Do not take TERTROXIN 20 µg:

- If you are hypersensitive (allergic) to liothyronine sodium or any of the other ingredients of TERTROXIN 20 µg (listed in section 6).
- If you have angina (severe pain in the chest) or any heart and blood vessel disorder.
- If you have untreated hyperthyroidism (overactive thyroid).
- If you suffer from a condition called Addison's disease (condition where your adrenal gland does not produce enough steroid hormones).

Warnings and precautions

Take special care with TERTROXIN 20 µg:

- If you have diabetes and are using antidiabetic medicines.
- If you have a condition where your adrenal glands do not produce enough of the hormone called cortisol (adrenocortical insufficiency).

- If you suffer from a condition called myxoedema (swelling of the skin and underlying tissues giving a waxy consistency, typical of patients with underactive thyroid glands).
- If you suffer from prolonged hypothyroidism (a condition in which the thyroid gland doesn't produce enough thyroid hormone).
- If you are using medication that prevents blood clotting.
- If you suffer from chest pain, fast heartbeat or excessive sweating.
- If you are an elderly person.

TERTROXIN 20 µg should not be used in the management of obesity as this may produce serious or life-threatening adverse effects.

Children and adolescents

A condition called craniosynostosis, where the sutures of the skull close too early causing problems with normal brain and skull growth, may occur in infants given high doses of thyroid hormones.

Partial hair loss can also occur in children in the first few months of thyroid therapy, but their hair may grow back.

Other medicines and TERTROXIN 20 µg

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Medicines used to thin your blood and to prevent blood clots e.g. aspirin.

- Anticonvulsants (e.g. carbamazepine, primidone or phenytoin) used to prevent convulsions (fits).
- Medicines used during anaesthesia such as ketamine.
- Oral contraceptives or other estrogen containing products.
- Medicines called digoxin used to treat heart conditions such as heart failure or amiodarone, used to treat irregular heartbeats.
- Colestyramine which reduces the level of cholesterol (fats) in the blood.
- Tricyclic antidepressants (e.g. amitriptyline or imipramine) used to treat depression.
- Insulin and other treatments for diabetes.

Pregnancy, breastfeeding and fertility

There is not enough information on the safe use of TERTROXIN 20 µg in pregnancy and breastfeeding

Liothyronine, as contained in TERTROXIN 20 µg, is excreted in breast milk.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking TERTROXIN 20 µg.

Driving and using machines

TERTROXIN 20 µg is expected to influence your ability to drive. Since adverse reactions such as headaches have been reported in patients receiving TERTROXIN 20 µg, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that TERTROXIN 20 µg does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent TERTROXIN 20 µg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TERTROXIN 20 µg affects you (see section 4).

TERTROXIN 20 µg contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TERTROXIN 20 µg.

3. How to take TERTROXIN 20 µg

Do not share medicines prescribed for you with any other person.

Always take TERTROXIN 20 µg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe an individualised dose for your specific condition.
Your doctor will tell you how long your treatment with TERTROXIN 20 µg will last.
If you have the impression that the effect of TERTROXIN 20 µg is too strong or too weak, tell your doctor or pharmacist.

If you take more TERTROXIN 20 µg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The following signs and symptoms indicate overdosage, and usually disappear when the dose is reduced, or treatment is withdrawn for a day or two; chest pain, irregular or abnormal heartbeat (cardiac dysrhythmias), feeling like your heart is racing(palpitation),

and cramps in skeletal muscle; also, fast heartbeat (tachycardia), diarrhoea, restlessness, irritability, nervousness, excitability, headache, reddening of the skin (flushing), sweating, excessive loss of weight and muscular weakness. Congestive heart failure (when the heart muscle doesn't pump blood as well as it should) may be induced or aggravated.

If you forget to take TERTROXIN 20 µg

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of TERTROXIN 20 µg, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

TERTROXIN 20 µg can have side effects.

Not all side effects reported for TERTROXIN 20 µg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TERTROXIN 20 µg, please consult your healthcare provider for advice.

If any of the following happens, stop taking TERTROXIN 20 µg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing as you could be suffering from a condition called myxoedema,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TERTROXIN 20 µg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Irregular heartbeat, abnormal heart beats, increased rate of heartbeat,
- Squeezing, pressure, heaviness, tightness or pain in the chest (anginal pain).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Cramps in the skeletal muscle, muscle weakness,
- excessive loss of weight,
- the inability to rest or relax or excitability,
- headache,
- reddening of the face and/or neck (flushing),
- frequent/loose watery stools (diarrhoea),
- sweating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27(0)11 239-6200

By reporting side effects, you can help provide more information on the safety of TERTROXIN 20 µg.

5. How to store TERTROXIN 20 µg

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TERTROXIN 20 µg contains

The active substance is 20 µg liothyronine sodium per tablet.

The other ingredients are acacia powder, lactose, magnesium stearate, maize starch, sodium chloride.

Contains sugar: Lactose monohydrate 48,5 mg

What TERTROXIN 20 µg looks like and contents of the pack

TERTROXIN 20 µg is a white, uncoated biconvex tablet with breakline and embossed with “TERTROXIN” and “GLAXO”.

50 tablets are packed in an amber vial and sealed with a plastic semi opaque white polyethylene snap cap, together with a white barrel shaped polyurethane foam insert.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Application number

G 3082 (Act 101/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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