1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

NEOMERCAZOLE 5 mg tablets

Carbimazole

Contains sugar: Sucrose 139,39 mg, lactose 30 mg

Read all of this leaflet carefully before you start taking NEOMERCAZOLE

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

1. What NEOMERCAZOLE is and what it is used for

NEOMERCAZOLE contains the active substance carbimazole.

NEOMERCAZOLE

NEOMERCAZOLE is used for people with an over-active thyroid gland (called 'hyperthyroidism').

- It works by reducing the amount of thyroid hormones made in your thyroid gland.
- It can be used on its own, or with other treatments for an over-active thyroid gland.
- It can also be used before part of the thyroid gland has been removed by surgery. It helps the thyroid gland work properly before the surgery.

2. What you need to know before you take NEOMERCAZOLE

Do not take NEOMERCAZOLE:

- If you are hypersensitive (allergic) to carbimazole or any of the other ingredients of NEOMERCAZOLE (listed in section 6).
- If you are allergic to other anti-thyroid medicines such as thiamazole or propylthiouracil.
- If you have liver problems.
- If you have problems with your blood cells.
- If you have any degree of tracheal obstruction as high doses may produce thyroid enlargement and obstructive symptoms may become marked.
- If you are pregnant, breastfeeding your baby or if you are planning to become pregnant (see section Pregnancy, breastfeeding and fertility).
- If you feel severe pain in your abdomen, as this may be a sign of acute pancreatitis.

Warnings and precautions

Take special care with NEOMERCAZOLE:

- Check with your doctor or pharmacist before taking your medicine if you develop mouth ulcers or sore throat, bruising or bleeding, general discomfort or fever, this may be due to abnormal findings in the blood. Seek medical advice immediately.
- Your doctor may do blood tests to monitor your thyroid function before you start NEOMERCAZOLE and while you are taking NEOMERCAZOLE.

Children

There is no experience with NEOMERCAZOLE in children.

Other medicines and NEOMERCAZOLE

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 to thin your blood or to stop clotting.
- Medicine to help your breathing called “theophylline.”
- Medicine that can cause decrease in white blood cells.
- Medicine used to treat heart conditions called digoxin and amiodarone.

Note that NEOMERCAZOLE can influence laboratory investigations i.e. liver enzymes.

Pregnancy, breastfeeding and fertility

You should not take NEOMERCAZOLE if you are pregnant or breastfeeding your baby. There is a chance that your baby may be affected (see section Do not take NEOMERCAZOLE).

Women of childbearing potential should use effective contraception and not plan to become pregnant when treated with NEOMERCAZOLE.

Do not breastfeed if you are taking NEOMERCAZOLE. This is because small amounts may pass into the mother's 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 this medicine.

Driving and using machines

Headache has been reported with the use of NEOMERCAZOLE, which can affect concentration.

It is not always possible to predict to what extent NEOMERCAZOLE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NEOMERCAZOLE affects them (see section 4).

NEOMERCAZOLE contains sucrose and lactose

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

3. How to take NEOMERCAZOLE

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

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

The usual dose of NEOMERCAZOLE is 10 mg to 60 mg daily according to the severity of the disorder. The dose should be gradually reduced to the smallest amount which will control the disease.

Your doctor will tell you how long your treatment with NEOMERCAZOLE will last. If you have the impression that the effect of NEOMERCAZOLE is too strong or too weak, tell your doctor or pharmacist.

If you take more NEOMERCAZOLE 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.

If you forget to take NEOMERCAZOLE

Take your missed dose as soon as you remember, if within a few hours after missing a dose. If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten individual dose.

4. Possible side effects

NEOMERCAZOLE can have side effects.

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

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

- hypersensitivity reactions such as effects on liver, lungs, renal system, blood vessels of the skin;
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- skin rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to NEOMERCAZOLE. 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:

- effects on bone-marrow including decrease in white and red blood cells as well as platelets,
- abnormal liver function tests - NEOMERCAZOLE may have to be stopped,
- disease of the immune system called “lupus-like” syndrome,
- bleeding, inflammation of smaller blood vessels,
- inflammation of the kidneys,
- severe pain in your abdomen, as this may be a sign of swelling of your pancreas (pancreatitis),
- realising you are pregnant as there have been reports of damage to the unborn baby (teratogenicity).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- nausea, vomiting and abdominal discomfort (stomach upset),
- skin pigmentation, hives.

Less frequent side effects:

- painful joints and muscle pain, Your doctor will advise on possible laboratory investigations,
- bruising.

Side effects with an unknown frequency

- “pins and needles” sensation,
- changes in taste,
- abnormal hair loss,
- fever.

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store NEOMERCAZOLE

Store all medicines out of reach of children.

Store in a cool place at or below 25 °C.

Keep tightly closed. 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 NEOMERCAZOLE contains

The active substance is 5 mg of carbimazole.

The other ingredients are acacia, gelatin, iron oxide red (C.I. 77941), lactose, magnesium stearate, starch maize, sucrose, talc purified.

What NEOMERCAZOLE looks like and contents of the pack

Pale pink, circular, biconvex, mottled tablet, engraved “Neo/5” on one side. When broken into two it contains a white inner core which is centrally placed.

100 tablets are packed in a 30 ml round, white high density polyethylene bottle with a threaded neck and sealed with a round, white polypropylene tamper-evident screw cap with

an integrated silica gel desiccant.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

TBA

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