

NEOMERCAZOLE® TABLET

Carbimazole (5mg)

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What NeoMercazole is used for

NeoMercazole is used to people with an overactive thyroid gland. The condition is called hyperthyroidism. NeoMercazole is also used in more serious cases as therapy prior to and post radio-iodine treatment.

How NeoMercazole Works

Carbimazole is thyroid reducing agent. NeoMercazole is used to reduce the formation of thyroid hormones.

Before you use NeoMercazole

- When you must not use it

- If you are allergic to thiamazole or propylthiouracil.
- If you are allergic (hypersensitive) to carbimazole or any of the ingredients of NeoMercazole.
- If you are breast-feeding.
- If you have a serious blood disorder.
- If you have a severe liver disorder.

- Before you start use it

- If you are pregnant, think you may be pregnant or are trying to become pregnant.
- If you have mild or moderate liver problems.
- If you have a swelling of the neck resulting from enlargement of the thyroid gland. Regular full blood count checks should be carried out in people who may be confused or have a poor memory.
- Tell your doctor if any of the above applies to you.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, or the following:

- Theophylline used to treat asthma or breathing problems.
- Medicines called anticoagulants, which are used to thin the blood.

NeoMercazole contains lactose and sucrose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

How to use NeoMercazole

Always take NeoMercazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

- The tablets are to be taken by mouth. The initial dose is in the range 20-60mg,
- Final dosage is usually in the range 5 - 15mg per day, which may be taken as a

single daily dose.

- The dosage will be decided by your doctor according to your individual needs, and may be changed at intervals during treatment.
- Your doctor may decide to add an additional tablet (l-thyroxine), to help control your condition. Children: the usual starting dose is three 5 mg tablets daily.

- When to use it

- Do not change the dosage frequency without consulting your doctor first.

- How long to use it

- In order to maintain control of the thyroid gland, you may need to continue to take NeoMercazole tablets for at least 6 and up to 18 month. Your doctor will decide when treatment can be stopped. He may ask you to have occasional blood tests to help him determine how you are responding to treatment.

- If you forget to use it

If you forget to take NeoMercazole take the next dose as soon as you remember. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you take more NeoMercazole than you should, contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you

If at any time you are concerned about these or any other unwanted effects, talk to your doctor as soon as possible.

While you are using it

- Things you must do

Your NeoMercazole treatment is important for you and may need to be continued during pregnancy but very rarely it can cause harm to a developing foetus.

- Your doctor should prescribe the lowest dose possible.
- Ask your doctor for advice before taking any medicine.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give NeoMercazole to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Driving and using machines:

You can drive when taking NeoMercazole, but do not drive until you know how it affects you.

- Pregnancy and breast-feeding

Your treatment may be discontinued three to four weeks before you are due to give birth.

You should not breast-feed if you are using NeoMercazole.

Side Effects

Like all medicines, NeoMercazole can cause side effects, although not everybody will experience them.

If you experience any of these symptoms whilst taking NeoMercazole please stop the medicines and contact your doctor immediately:

- sore throat
- mouth ulcers
- fever
- bruising or bleeding
- you are feeling generally unwell or think that you may have an infection

Some tests should be performed to check for bone marrow depression before restarting your treatment.

Bone marrow depression causes a reduction in the number of blood cells and reduces the ability to fight infection. If it is not treated as soon as it is detected the condition can become life-threatening.

NeoMercazole can also affect the liver (causing jaundice and inflammation of the liver) or the muscles. If you experience muscle aches or pains or notice yellowing of your skin or the whites of your eyes consult your doctor immediately as, under medical supervision, the medicine should be stopped and blood tests performed.

Most frequent side effects include:

- feeling sick
- headache
- skin rashes, including (nettle rash)
- itching
- stomach upset
- painful joints.

The following side effects have also been reported:

- hair loss
- loss of taste
- swelling under the skin
- a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat

You may report any side

effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effect to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of NeoMercazole

- Storage

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original container.

- Disposal

Do not use after the expiry date which is printed on the carton after EXP. The expiry date refers to the last day of that month.

Product Description

- What it look like

NeoMercazole tablets are pink, circular biconvex, imprinted with Neo 5 on the obverse and plain on the reverse.

- Ingredients

-Active ingredient: Each tablet contains carbimazole 5mg.

-Inactive ingredient:

Lactose, Maize Starch, Gelatin, Magnesium Stearate, Sucrose, Acacia, Talc, Red Iron Oxide (E172).

- MAL Number:

MAL12020025ACZ

Manufacturer

Cenexi, 52 rue Marcel et Jacques Gaucher, 94120 Fontenay Sous Bois, France

Product Registration Holder:

A.Menarini Singapore Pte. Ltd.
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