

NEO-MERCAZOLE[®]

Carbimazole 5 mg tablets

What is in this leaflet

This leaflet answers some common questions about NEO-MERCAZOLE[®] tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NEO-MERCAZOLE[®] against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What NEO-MERCAZOLE[®] is used for

NEO-MERCAZOLE[®] contains the active ingredient carbimazole.

NEO-MERCAZOLE[®] is used to reduce the formation of thyroid hormones in people with an over- active thyroid gland. The condition is called hyperthyroidism. NEO-MERCAZOLE[®] may be used alone or together with other treatments for hyperthyroidism.

NEO-MERCAZOLE[®] may also be used to restore the normal function of the thyroid before its partial removal by surgery, and before and after radio-active iodine treatment.

Your doctor, however, may have prescribed NEO-MERCAZOLE[®] for another purpose.

Ask your doctor if you have any questions why NEO-MERCAZOLE[®] has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take NEO-MERCAZOLE[®]

When you must not take it

Do not take NEO-MERCAZOLE[®] if:

1. you have had an allergic reaction to NEO-MERCAZOLE[®] or any ingredients listed at the end of this leaflet
2. you have a serious blood condition

3. you have a severe liver condition
4. you have swelling on the neck caused by enlargement of the thyroid gland
5. you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.
6. the package is torn or shows signs of tampering
7. the expiry date printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well
8. you are not sure if you should be taking NEO-MERCAZOLE[®], talk to your doctor.

Before you start to take it

Tell your doctor if you:

1. develop mouth ulcers or sore throat, bruising or bleeding, general discomfort or fever, this may be due to abnormal findings in the blood
2. have bone marrow depression
3. **are pregnant or plan to become pregnant**
Carbimazole can cause harm to an unborn baby. If you could get pregnant, use reliable contraception from the time you start treatment and during treatment. If there is a need to take NEO-MERCAZOLE[®] when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
4. **are breast-feeding or plan to breast-feed**
NEO-MERCAZOLE[®] passes into breast milk. You should not breast-feed if you are taking NEO-MERCAZOLE[®].
5. **have any other health problems, especially the following:**
 - liver disease
6. **are allergic to any other medicines, foods, dyes or preservatives**
7. are taking some medicines such as the ones which may cause blood disorders, blood thinners (See ***Taking other medicines***)
8. are receiving radio-iodine (for thyroid problems)
9. have swelling in your neck called an 'intrathoracic goitre'
10. have any degree of tracheal obstruction, as high doses may produce thyroid enlargement and obstructive symptoms may become marked
11. have muscle tenderness or weakness
12. are unable to comply with the instructions for use or cannot be monitored regularly
13. are lactose intolerant or have any other lactose deficiency
14. are sucrose intolerant or have any other sucrose deficiency
15. develop fever or abdominal pain, which may be signs of inflammation of the pancreas (acute pancreatitis). NEO-MERCAZOLE[®] may need to be discontinued.

If you have not told your doctor about any of the above, do so before you start taking NEO-MERCAZOLE[®].

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with NEO-MERCAZOLE[®]. These include:

- Theophylline: medicines to help your breathing
- Steroids such as prednisolone, which reduce the activity of your immune system
- Erythromycin: medicines used to treat infections.
- Digoxin and amiodarone: medicine used to treat heart conditions
- Antihypertensive (e.g. beta blockers): medicines used to treat high blood pressure
- Medicine that can cause decrease in white blood cells
- Anticoagulants: medicines which are used to thin your blood or to stop clotting
- Sodium iodide 1131: medicines used to treat thyroid gland tumours and over-activity of the thyroid gland

These medicines may be affected by NEO-MERCAZOLE[®], or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Note that NEO-MERCAZOLE[®] can influence laboratory investigations, i.e. liver enzymes, bleeding time.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NEO-MERCAZOLE[®].

Ask your doctor or pharmacist if you are not sure about taking other medicines.

How to take NEO-MERCAZOLE[®]

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Take NEO-MERCAZOLE[®] exactly as your doctor has prescribed.

Your doctor will tell you how many NEO-MERCAZOLE[®] tablets to take each day.

The dosage will be decided according to the severity of your condition and your individual needs, and may be changed at intervals during treatment.

The usual adult starting dose is four to twelve 5 mg tablets each day, in divided doses.

For children, the usual starting dose is three 5 mg tablets each day, in divided doses.

Once control is achieved your doctor may gradually reduce your dose. The usual maintenance dose is two to three 5 mg tablets each day.

How to take it

Swallow tablets whole with a glass of water or other liquid.

When to take it

Each day's tablets may be divided evenly into two (morning and evening), or three (morning, noon and night) daily doses.

Take your NEO-MERCAZOLE[®] at about the same times each day.

It does not matter if you take NEO-MERCAZOLE[®] with food or not. Taking your medicine at the same time each day will have the best effect. It will also help you to remember when to take the tablets.

How long to take it

There can be large differences in the amount of time NEO-MERCAZOLE[®] takes to start working, depending on your condition. There should be some improvement within three months of starting your NEO-MERCAZOLE[®] treatment.

In order to maintain control of the thyroid gland, you may need to continue to take NEO-MERCAZOLE[®] tablets for several months or years.

Continue taking NEO-MERCAZOLE[®] until your doctor tells you to stop.

Radio-iodine is another treatment for hyperthyroidism. If you need radio-iodine treatment, your doctor may tell you to stop taking NEO-MERCAZOLE[®] temporarily.

If you forget to take it

If you miss a dose take it as soon as you remember. If your next dose is due, take both doses together.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

In case of an overdose

Immediately telephone your doctor, or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to your nearest Accident and Emergency Centre, if you think you or anyone else may have taken too much NEO-MERCAZOLE[®]. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking NEO-MERCAZOLE®

Things you must do

IMPORTANT

If you suffer from any infection, especially a sore throat or mouth ulcers, a fever, unexplained bleeding or bruising while you are taking NEO-MERCAZOLE®, stop taking the tablets and report this **immediately** to your doctor. Blood tests may be performed to check if there are any problems with your bone marrow before restarting your treatment.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEO-MERCAZOLE®.

Tell your doctor if you become pregnant while taking NEO-MERCAZOLE®. Carbimazole can cause harm to an unborn baby. If you could get pregnant, use reliable contraception from the time you start treatment and during treatment.

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor straight away. Your treatment with carbimazole may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may ask you to have occasional blood tests to help determine how you are responding to treatment.

Things you must not do

Do not stop taking NEO-MERCAZOLE® or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give NEO-MERCAZOLE® to anyone else even if they have the same condition as you.

Do not use NEO-MERCAZOLE® to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how NEO-MERCAZOLE® affects you.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEO-MERCAZOLE®.

NEO-MERCAZOLE® helps most people with hyperthyroidism but it may have unwanted side effects in some people.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea
- headache
- painful joints
- stomach upset
- skin rashes
- itching

These are the more common side effects of NEO-MERCAZOLE®, and usually occur in the first 8 weeks of treatment. Mostly these are mild and should decrease as you get used to your medicine.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- Angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips face or throat.
- Swelling, hypersensitivity reactions such as effects on liver, lungs, kidney, blood vessels of the skin.
- Aching muscles, muscle tenderness or weakness not caused by exercise.
- Yellowing of your skin and/or the whites of your eyes.
- Hepatitis (a liver disease. *Symptoms:* nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine).
- Abnormal liver function tests – NEO-MERCAZOLE® may have to be stopped.
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers tiredness, headaches, being short of breath when exercising, dizziness and looking pale.
- Bleeding or bruising more easily than normal, nosebleeds.

If you suffer from any infection, especially a sore throat or mouth ulcers, a fever,

unexplained bleeding or bruising while you are taking NEO-MERCAZOLE®, stop taking the tablets and report this **immediately** to your doctor. Blood tests may be performed to check if there are any problems with your bone marrow before restarting your treatment.

These may be serious side effects. You may need urgent medical attention.

Other side effects:

- Swelling of lymph nodes
- Low sugar (glucose) levels in the blood (*symptoms*: sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat)
- “Pins and needles” sensation
- Dizziness
- Nerve pain
- Brain disease (not otherwise specified)
- Loss of taste
- Eyes sticking out too far (exophthalmos)
- Bleeding
- Vomiting
- Muscle pain. Your doctor will advise on possible laboratory investigations.
- Skin pigmentation, hives, abnormal hair loss, redness of skin
- Stevens-Johnson syndrome (rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals)
- Fever, generally feeling unwell, exhaustion
- Bruising
- Hair loss
- Swelling of glands in your mouth
- Boils
- Inflammation of the pancreas (acute pancreatitis)

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything on this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking NEO-MERCAZOLE®

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep NEO-MERCAZOLE® in a cool dry place where the temperature stays below 25 °C.

Do not store it or any other medicine in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep NEO-MERCAZOLE® where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEO-MERCAZOLE®, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

Availability

NEO-MERCAZOLE® comes in one tablet strength, 5 mg.

NEO-MERCAZOLE® comes in packs of 100 tablets.

What NEO-MERCAZOLE® looks like

Pale pink circular tablets, with shallow biconvex faces and white centrally located core. One side is imprinted Neo 5. The other side is blank.

Ingredients

Active ingredient

- carbimazole 5 mg

Inactive ingredients

- lactose, maize starch, sucrose, magnesium stearate, talc, gum acacia, ferric oxide, propyl hydroxybenzoate, gelatin.

Patients with lactose or sucrose intolerance should avoid this product as it contains

lactose monohydrate and sucrose.

Distributor

NEO-MERCAZOLE® is distributed by:
AFT Pharmaceuticals Ltd
P.O. Box 33-203
Takapuna
AUCKLAND
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