

NeoMercazole® 5mg Tablets / Carbimazole 5mg Tablets

(carbimazole)

Your medicine is known by one of the above names, but will be referred to as Carbimazole throughout this:

Patient Information Leaflet

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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1) What Carbimazole is and what it is used for

Carbimazole belongs to a group of medicines called anti-thyroid medicine. Carbimazole is used for adults and children with an over-active thyroid gland (called 'hyper-thyroidism')

- 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 Carbimazole

Do not take Carbimazole if:

- You are allergic (hypersensitive) to carbimazole or any of the ingredients of Carbimazole tablets (listed in Section 6)
- You are allergic (hypersensitive) to other anti-thyroid medicines such as thiamazole, methimazole or propylthiouracil
- You are breast-feeding.
- You have a severe liver disorder
- You have a serious blood disorder.

Do not take Carbimazole tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Carbimazole.

Warnings and precautions

Take special care with Carbimazole

Check with your doctor or pharmacist before taking your medicine if:

- You have a swelling in your neck called an 'intrathoracic goitre'
- You are pregnant, think you may become pregnant or are trying to become pregnant
- You have bone marrow depression
- You have mild or moderate liver problems
- You are receiving radio-iodine (for thyroid problems)
- You are of child bearing potential
- You are allergic to thiamazole, methimazole or propylthiouracil (other thyroid medications)
- You are lactose intolerant or have any other lactose deficiency
- You are unable to comply with the instructions for use or cannot be monitored regularly.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking Carbimazole.

Children

Do not give this medicine to children under the age of two years because it may not be safe or effective.

Other medicines and Carbimazole

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines obtained without a prescription, including herbal medicines. This is because Carbimazole can affect the way some medicines work. Also some medicines can affect the way Carbimazole works.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Medicines to thin your blood or to stop clotting
- A medicine to help your breathing called 'theophylline'
- Steroids such as prednisolone
- An antibiotic called erythromycin
- A medicine for heart failure called digitalis
- Medicines for high blood pressure called beta-blockers.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Carbimazole.

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. This is because there is a very small chance that your baby may be affected.

In some cases, your doctor may prescribe Carbimazole while you are pregnant. He or she will talk to you about this. If they do, they will lower the possibility of any effects on your baby by:

- Using the lowest possible dose
 - Stopping treatment three to four weeks before you are due to give birth.
- Do not breast-feed if you are taking Carbimazole. This is because small amounts may pass into the mother's milk.

Driving and using machines

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

Carbimazole tablets contain lactose

If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3) How to take Carbimazole

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- You can take the tablets before, during or after meals
- The tablets you take each day may be split into two (morning and evening) or three (morning, afternoon and night). Ask your pharmacist if you are not sure.

How much to take at the start

The doctor will decide on a starting dose, and then see how well it works.

- If needed, he or she will then change the dose
- This is to find a dose that suits you best.

Adults

The recommended starting dose for the 5 mg tablets is between 4 and 12 tablets each day.
The recommended starting dose for the 20 mg tablets is between 1 and 3 tablets each day.

Use in children

The recommended starting dose is three 5 mg tablets each day.

How much to take after the starting dose

Your illness will usually start to improve within one to three weeks. However, it usually takes four to eight weeks to have full benefit from your treatment.

- When your illness is controlled, your doctor will gradually lower your dose to one to three 5 mg tablets each day
- Do not change your dose without talking to your doctor first.

You may need to keep taking Carbimazole for several months to keep control of your thyroid gland. Your doctor will decide when treatment can be stopped. Your doctor may ask you to have occasional blood tests to see how well your treatment is working.

Your doctor may decide to add an additional tablet (l-thyroxine), to help control your condition.

Radio-iodine

Another treatment for an over-active thyroid is called "radio-iodine". If you need radio-iodine treatment your doctor will tell you to stop taking Carbimazole tablets for a while.

If you take more Carbimazole than you should

If you take more Carbimazole than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack or this leaflet and any remaining tablets with you.

If you forget to take Carbimazole

If you forget a dose, take it as soon as you remember. If it is time for your next dose, take both doses together.

4) Possible side effects

Like all medicines, Carbimazole can cause side effects, although not everybody gets them. The side effects usually happen in the first eight weeks of your treatment.

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

Allergic reactions

If you have an allergic reaction, stop taking Carbimazole and see a doctor straight away. The signs may include: sudden rash, swelling or difficulty breathing.

Stop taking Carbimazole and see a doctor straight away, if you notice any of the following side effects:

- Any infection such as a sore throat or mouth ulcers
 - Fever
 - Unusual bruising or bleeding
 - Feeling unusually tired
 - You are feeling generally unwell or think that you may have an infection.
- Your doctor may need to do some tests to check for something called 'bone marrow depression' before you start your treatment again.

Tell your doctor if you get any of the following side effects:

- Liver problems such as yellowing of the skin or eyes (jaundice)
- Muscle pain or weakness
- Nerve pain
- Swelling of lymph nodes
- Swelling of glands in your mouth
- Feeling faint (low blood sugar).

Other side effects include:

If you get any of the following side effects, they normally go away while you keep taking your medicine.

- Feeling sick (nausea)
- Headache or feeling dizzy
- Skin rashes
- Itching
- Stomach upset
- Painful joints
- Hair thinning
- Changes to your taste.

The following side effects have also been reported:

- Angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat
- Lung problems, with symptoms that include shortness of breath or a cough
- Kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine.

Reporting 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. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Carbimazole

- Keep all medicines out of the sight and reach of children.
- Do not use after the expiry date printed on the carton, and bottle label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original container.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of 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) Content of the pack and other information

What Carbimazole contains:

The active substance is carbimazole. Each tablet contains 5mg carbimazole.

The other ingredients are sucrose, lactose monohydrate, acacia, talc, maize starch, magnesium stearate, gelatin and red iron oxide (E172).

What Carbimazole looks like and content of the pack

Carbimazole 5mg tablets are pink, round, biconvex, uncoated tablets with Neo 5 stamped on one side and plain on the other.

Carbimazole 5mg is available in plastic bottles of 100 tablets.

PL 10383/2065 Carbimazole 5mg Tablets /
NeoMercazole 5mg Tablets

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Who makes and repackages your medicine

Your medicine is manufactured by Amdipharma Plc., Regency House, Miles Gray Road, Basildon, Essex, SS14 3AF, UK or Cenexi SAS, 52 rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France. Procured from within the EU and repackaged by Product Licence Holder: Primecrown Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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