



Carbimazole 5 mg, 10 mg, 15 mg and 20 mg tablets

F1615

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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 CARBIMAZOL IS AND WHAT IT IS USED FOR

Carbimazole belongs to a group of medicines called 'anti-thyroid' medicines.

It 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 to carbimazole or any of the other ingredients of this medicine (listed in Section 6).
- You have a severe liver disorder.
- You have a serious blood disorder.
- If you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.

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

Talk to your doctor or pharmacist before taking Carbimazole 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 unable to comply with the instructions for use or cannot be monitored regularly.
- Tell your doctor straight away if you develop fever or abdominal pain, which may be signs of inflammation of the pancreas (acute pancreatitis). Carbimazole may need to be discontinued.
- 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 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 (anticoagulants) e.g. warfarin.
- A medicine used to treat asthma or breathing problems 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.
- Any other medicine that could affect your white blood cell count.

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.

Pregnancy

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.

However, to reduce the possibility of any effects on your baby:

- Your doctor should prescribe the lowest possible dose.
- Your treatment may be discontinued three to four weeks before you are due to give birth.

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.

Breast-feeding

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 have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE CARBIMAZOLE

Always take this medicine exactly as your doctor has told you. 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 is 20 mg to 60 mg each day.

The number of tablets to be taken depends on the tablet you have been given. This would usually be between:

- 1 and 3 tablets for the 20 mg tablet
- 2 and 6 tablets for the 10 mg tablet
- 4 and 12 tablets for the 5 mg tablet.

Use in children

The recommended starting dose is 15 mg each day. This would usually be three 5 mg tablets or one 15 mg tablet.

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 or one 15 mg tablet 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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.
- Angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat.
- Stevens-Johnson syndrome, a serious illness with blistering of the skin, mouth, eyes and genitals.

In addition, if you experience any of these symptoms while taking Carbimazole you should also **contact your doctor immediately**:

- Liver problems such as yellowing of the skin or whites of your eyes (jaundice).
- Muscle pain or weakness.
- Nerve pain.
- Swelling of lymph nodes.
- Swelling of glands in your mouth.
- Feeling faint (low blood sugar).
- Kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine.

These could be signs of muscle problems, jaundice or inflammation of the liver and under medical supervision your doctor may want you to stop taking the medicine and carry out some blood tests on you.

Do not stop taking Carbimazole until you have consulted your doctor.

Carbimazole can sometimes cause bone marrow depression which 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. Your doctor should carry out tests to check for bone marrow depression before restarting your treatment.

The following side effects are reported with a not known frequency (frequency cannot be estimated from the available data):

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, including urticaria (nettle rash)
- Itching
- Stomach upset
- Painful joints.

The following side effects have also been reported:

- Hair thinning
- Changes to your taste
- Inflammation of the pancreas (acute pancreatitis)
- Lung problems, with symptoms that include shortness of breath or a cough.

Reporting of 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE CARBIMAZOLE

- **Keep this medicine out of the sight and reach of children.**
- Do not use Carbimazole after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store Carbimazole in the original packaging.
- 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Carbimazole tablets contain

- The active ingredient is carbimazole. Each tablet contains 5mg or 10mg or 15mg or 20mg of carbimazole.
- The other ingredients are lactose anhydrous, magnesium stearate, croscarmellose sodium and the colourant red iron oxide (E172).

What Carbimazole tablets look like and contents of the pack

- Carbimazole 5 mg tablets are round, pale pink and marked with Link C5 on one side and have a scoreline on the reverse side.
- Carbimazole 10 mg tablets are round, pale pink and marked with C10 on one side and plain on the reverse side.
- Carbimazole 15 mg tablets are round, pale pink to pink and marked with C15 on one side and plain on the reverse side.
- Carbimazole 20 mg tablets are round, pink and marked with Link C20 on one side and have a scoreline on the reverse side.

Carbimazole 5 mg and 20 mg tablets are packed in cartons containing 28, 56, 100 or 112 tablets in a blister pack (not all pack sizes will be marketed).

Carbimazole 10 mg and 15 mg tablets are only packed in cartons containing 100 tablets in a blister pack.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Amdipharm UK Limited,
Capital House,
85 King William Street,
London EC4N 7BL,
UK

Manufacturer:

Central Pharma (Contract Packing) Limited
Caxton Road, Bedford, MK41 0XZ, UK

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