

PACKAGE LEAFLET: INFORMATION FOR THE USER
Carbimazole 10 mg Tablets
Carbimazole 15 mg Tablets
 carbimazole

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 onto 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 Tablet is and what it is used for
2. What you need to know before you take Carbimazole Tablet
3. How to take Carbimazole Tablet
4. Possible side effects
5. How to store Carbimazole Tablet
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1. What Carbimazole Tablet is and what it is used for

This belongs to a group of medicines called anti-thyroid agents. Carbimazole Tablets are used to reduce the formation of thyroid hormones in adults and children with an overactive thyroid gland. The condition is called hyperthyroidism. Carbimazole Tablets are also used in more serious cases, for example, to restore the normal function of the thyroid before its partial removal by surgery. It may also be used together with other treatments for hyperthyroidism.

2. What you need to know before you take Carbimazole Tablets

Do not take Carbimazole Tablets:

- If you are allergic (hypersensitive) to carbimazole or any of the other ingredients of this medicine (listed in Section 6).
- If you are allergic (hypersensitive) to other anti-thyroid medicines such as thiamazole, methimazole or propylthiouracil.
- If you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.
- If you are breast-feeding.
- If you have a serious blood disorder.
- If you have a severe liver disorder.

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbimazole Tablets

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

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

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 Tablets

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 Tablets can affect the way some medicines work. Also some medicines can affect the way Carbimazole Tablet works. In particular tell your doctor or pharmacist if you are taking any of the following:

- Theophylline used to treat asthma or breathing problems.
- Medicines used to thin your blood or to stop clotting (anticoagulants) e.g. warfarin.
- 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.

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 straight away before taking this medicine.

Pregnancy

Carbimazole Tablets 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 dose possible.
- Your treatment may be discontinued three to four weeks before you are due to give birth.

Your treatment with Carbimazole Tablets may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

Breast-feeding

You should not breast-feed if you are using Carbimazole Tablets. This is because small amounts may pass into the mother's milk.

Driving and using machines

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

Carbimazole Tablet contains lactose and sucrose

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 Tablets

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

- The tablets should be taken by mouth.
- You can take the tablets before, after or during meals.
- Each day's tablets may be divided into two (morning and evening) or three daily doses (morning, noon and night).

Adults and the elderly

The recommended starting dose is 20mg to 60mg each day. The number of tablets to be taken depends on the tablet you have been given. This would usually be between: one to three 20mg tablets or two to six 10mg tablets or four to twelve 5mg tablets. Once control is achieved your doctor will gradually reduce your dose to one to three 5 mg tablets each day or one 15mg tablet each day.

Use in Children

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

The dosage will be decided by your doctor according to your individual needs, and may be changed at intervals during treatment.

Do not change the dosage without consulting your doctor first.

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

Some improvement is usually felt within one to three weeks. However, full beneficial effects usually take four to eight weeks.

In order to maintain control of the thyroid gland, you may need to continue to take Carbimazole Tablets for several months. Your doctor will decide when treatment can be stopped. They may ask you to have occasional blood tests to help them to determine how you are responding to treatment.

Radio-iodine is another treatment for hyperthyroidism. If you need radio-iodine treatment, your doctor will tell you to stop taking Carbimazole Tablets temporarily.

If you take more Carbimazole Tablets than you should

If you take more Carbimazole Tablets than you should, contact your doctor or go to a nearest hospital emergency department immediately. Take the medicine pack or this leaflet and any remaining tablets with you.

If you forget to take Carbimazole Tablets

If you forget to take Carbimazole Tablets take the next dose as soon as you remember. If your next dose is due, 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.

Allergic reactions

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

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

- Sore throat
- Mouth ulcers
- High temperature or Fever
- Significant tiredness
- Increased bruising or bleeding tendency
- You are feeling generally unwell or think that you may have an infection
- Stevens-Johnson syndrome, a serious illness with blistering of the skin, mouth, eyes and genitals
- angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat

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

- Muscle pain or weakness
- Nerve pain
- Swelling of lymph nodes
- Swelling of glands in your mouth
- Feeling faint (low blood sugar)
- Yellowing of your skin or whites of your eyes (jaundice)
- 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 Tablets until you have consulted your doctor.

Carbimazole Tablets 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):

- Feeling sick
- Headache
- Skin rashes, including urticaria (nettle rash)
- Itching
- Stomach upset
- Painful joints
- Hair loss
- Loss of taste
- Lung problems, with symptoms that include shortness of breath or a cough
- Inflammation of the pancreas (acute pancreatitis)

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 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 Tablets

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Carbimazole 10 mg and 15 mg Tablets contain

- The active substance is carbimazole. Each tablet contains 10 mg or 15 mg of carbimazole.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, citric acid monohydrate, sucrose, ferric oxide red (E172) and magnesium stearate.

What Carbimazole 10 mg and 15 mg Tablets looks like and contents of the pack

Carbimazole 10 mg: Pink coloured, speckled, round (approx. 6.00 mm), biconvex, uncoated tablets debossed '10' on one side and other side plain.

Carbimazole 15 mg: Pink coloured, speckled, round (approx. 6.80 mm), biconvex, uncoated tablets debossed with '15' on one side and plain on other side.

Carbimazole 10mg and 15mg Tablets are available in cartons containing Aluminium-PVC/PVDC blister packs of 28's, 56's, 100's and 112's along with a leaflet inside.

Not all pack sizes may be marketed.

Marketing Authorization Holder
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