

Package leaflet: Information for the patient

Carbimazole 5mg Tablets Carbimazole 20mg 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. 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.

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
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6. Contents of the pack and other information

1. What Carbimazole is and what it is used for

The name of your medicine is Carbimazole 5 mg Tablets or Carbimazole 20 mg Tablets (this will be referred to Carbimazole throughout the leaflet). Carbimazole contains the active ingredient carbimazole. Carbimazole belongs to a group of medicines called anti-thyroid agents. Carbimazole is used to reduce the formation of thyroid hormones in adults and children with an overactive thyroid gland. The condition is called hyperthyroidism. Carbimazole is 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

Do not take Carbimazole

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

Warnings and precautions

Ask your doctor or pharmacist for advice before taking any medicine.

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.

Take Special care with carbimazole

- If you have a swelling in your neck called an 'intrathoracic goiter'.
- If you have bone marrow depression.
- 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 unable to comply with the instructions for use or cannot be monitored regularly.

Talk to your doctor or pharmacist before taking Carbimazole

- If you are pregnant, think you may become pregnant or are trying to become pregnant.
- If you have mild or moderate liver problems.

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:

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

Pregnancy and breast-feeding

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.

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 contains lactose If your doctor has told you that you have an intolerance to some sugars, contact 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. Take special care with Carbimazole.

- The tablets should be taken by mouth.
- The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

- You can take the tablets before, after or during meals.
- The total number of tablets you take each day may be divided into two dosage intervals (morning and evening) or three intervals (morning, afternoon and night)

Adults and the elderly: The recommended starting dose is one to three 20 mg tablets, or four to twelve 5 mg tablets daily. Once control is achieved your doctor will gradually reduce your dose to one to three 5 mg tablets each day.

Use in children:

The recommended starting dose is three 5 mg tablets daily.

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

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

If you take more Carbimazole than you should

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

If you forget to take Carbimazole

If you forget to take Carbimazole 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 of the use of this medicine ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Carbimazole can cause side effects, although not everybody gets 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:

- 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.

In addition, if you experience any of these symptoms while taking Carbimazole 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

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.

Other side effects include:

- Feeling sick.
- Headache.
- Skin rashes, including urticaria (nettle rash).
- Itching.
- Stomach upset.
- Painful joints.

The following side effects have also been reported:

- Hair loss.
- Loss of taste.
- 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.

Not known (frequency cannot be estimated from the available data)

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Carbimazole

- **Keep out of the sight and reach of children.**
- This medicinal product does not require any special temperature storage conditions. Keep blister in outer carton in order to protect from light.
- 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.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.

- Medicines should not be disposed of via waste water 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 5 mg tablets contains

- The active ingredient is carbimazole. Each tablet contains 5 mg of carbimazole.
- The other ingredients are lactose, croscarmellose sodium & magnesium stearate.

What Carbimazole 20 mg tablets contains

- The active ingredient is carbimazole. Each tablet contains 20 mg of carbimazole.
- The other ingredients are lactose, croscarmellose sodium & magnesium stearate.

What Carbimazole 5 mg & 20 mg tablets looks like and contents of the pack

- Carbimazole 5 mg tablets are white, 6.30mm diameter round, uncoated tablets plain on one side and a break line on other side.
- Carbimazole 20 mg tablets are white, 9.60mm diameter, round, uncoated tablets plain on one side and a break line on other side
- Each carton contains 28, 56, 100 and 112 Tablets in a blister pack. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorized in the Member States of the EEA under the following names:

Carbimazole 5 mg Tablets

Carbimazole 20 mg Tablets

This leaflet was last revised in

July 2019