

PACKAGE LEAFLET

Package leaflet: Information for the user

Carbimazole 5 mg Tablets Carbimazole 20 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 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 Carbimazole is and what it is used for

The name of your medicine is Carbimazole 5 mg or 20 mg Tablets (this will be referred to as Carbimazole throughout this leaflet). Carbimazole contains the active substance 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 to carbimazole or any of the ingredients of this medicine (listed in section 6).
- If you are allergic to other anti-thyroid medications such as thiamazole, methimazole or propylthiouracil.
- If you have a serious blood disorder.
- If you have a severe liver disorder.
- If you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.

Warnings and precautions

Talk to your doctor or pharmacist before taking Carbimazole

- If you are pregnant, think you may be pregnant or are trying to become pregnant.
- If you have mild or moderate liver problems.
- If you have bone marrow depression. Bone marrow depression causes a reduction in the number of blood cells and reduces the ability to fight infection.
- 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 have a swelling in your neck called an 'intrathoracic goitre'.
- If 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:

- 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 (digoxin)
- 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 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 dose possible.
- 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

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

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

Driving and using machines

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

Carbimazole contains 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 Carbimazole exactly as your doctor 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.
- The dosage will be decided by your doctor according to your individual needs, and may be changed at intervals during treatment.
- Your doctor may decide to add an additional tablet (l-thyroxine), to help control your condition.
- Each day's tablets may be divided into two (morning and evening) or three daily doses (morning, noon and night).
- **Do not** change the dosage without consulting your doctor first.
- 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 radioiodine treatment, your doctor will tell you to stop taking Carbimazole temporarily.

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.

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 on 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
- itching
- increased bruising or bleeding tendency
- 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**:

- 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 of the amount of urine passed, fluid retention, blood in the urine and yellowing of your skin or whites of your eyes.

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

Some tests should be performed to check for bone marrow depression before restarting your treatment. Bone marrow depression 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.

Carbimazole can also affect the liver (causing jaundice and inflammation of the liver) or the muscles. If you experience muscle aches or pains or notice yellowing of your skin or the whites of your eyes **consult your doctor immediately** as, under medical supervision, the drug should be stopped and blood tests performed.

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

Other side effects include:

- feeling sick
- feeling unusually tired
- headache
- skin rashes, including urticaria (nettle rash)
- itching
- stomach upset
- painful joints.

The following side effects have also been reported:

- hair thinning
- loss of taste
- inflammation of the pancreas (acute pancreatitis)
- lung problems, with symptoms that include shortness of breath or 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:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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 store your tablets above 25°C. Store in the original package.

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.

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 contains

- The active substance is carbimazole. Each tablet contains 5 mg or 20 mg of carbimazole.
- The other ingredients are: starch, pregelatinized, lactose, anhydrous, citric acid monohydrate and magnesium stearate.

What Carbimazole looks like and contents of the pack

Carbimazole 5 mg Tablets are 5.2 mm, white, circular-shaped, flat-faced, beveled edge uncoated tablets debossed with “5” on one side and “C” on other side.

Carbimazole 20 mg tablets are 8.5 mm, white, circular-shaped, biconvex, uncoated tablets debossed with “20” on one side and “C” on other side.

Carbimazole Tablets are available in blister packs containing 10 (1 x 10), 14 (1 x 14), 28 (2 x 14), 42 (3 x 14), 56 (4 x 14), 84 (6 x 14), 100 (10 x 10) or 112 (8 x 14) tablets, or in white high-density polyethylene bottles (with child-resistant closure) containing 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Renata Pharmaceuticals (Ireland) Limited, 13-18 City Quay, Dublin 2, Ireland.

Manufacturer

Alterno Labs d.o.o., Brnčičeva ulica 29, Ljubljana-Črnuče, 1231, Slovenia.

Distributed by:

Azure Pharmaceuticals Ltd, Blackrock, Co. Louth, Ireland.

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

Ireland	Carbimazole 5 mg & 20 mg Tablets
Malta	Carbimazole 5 mg & 20 mg Tablets

This leaflet was last revised in August 2022.