



Package leaflet:
Information for the patient

Carbimazole 5 mg tablets

Carbimazole 20 mg tablets

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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 is a sulfur-containing imidazole derivative which 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 over active 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 like therapy prior to and post radio-iodine treatment.

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).
- 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 have a swelling in your neck called an 'intrathoracic goitre'.
- 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 unable to comply with the instructions for use or cannot be monitored regularly.
- If you are pregnant, think you may be pregnant or are trying to become pregnant.
- If you have mild or moderate liver problems.
- 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.
- 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 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 monohydrate

Carbimazole tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Carbimazole tablet contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Carbimazole

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 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 score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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 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, this medicine 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 in 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
- 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 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
- Kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention, 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 number of blood cells and reduces the ability to fight against 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
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 this medicine after the expiry date which is stated on the label, carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use this medicine if you notice any change in the appearance of the tablets.

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 to protect the environment.

6. Contents of the pack and other information

What Carbimazole contains

- The active substance is Carbimazole.

Carbimazole 5 mg tablets

Each tablet contains 5 mg Carbimazole.

Carbimazole 20 mg

tablets Each tablet contains 20 mg Carbimazole.

- The other ingredients are: Lactose monohydrate, croscarmellose sodium, Iron oxide red (E172) and magnesium stearate.

What Carbimazole looks like and contents of the pack

Carbimazole 5 mg tablets

Pink colored, mottled, uncoated, circular [diameter 5 mm], biconvex tablets debossed with "C5" on one side "break line" on other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Carbimazole 20 mg tablets

Pink colored, mottled, uncoated, circular [diameter 8.3 mm], biconvex tablets debossed with "C 20" on one side and "break line" on other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Carbimazole tablets are available in blister packs.

Pack sizes

Blister packs: 100 tablets.

Marketing Authorisation Holder

Milpharm Limited
Ares Block, Odyssey Business Park
West End Road, Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000, Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park,
West End Road, Ruislip HA4 6QD,
United Kingdom

or

Generis Farmaceutica, S.A.
Rua João de Deus, n. o 19,
Venda Nova, 2700-487,
Amadora, Portugal

This leaflet was last revised in 01/2023.