

Package leaflet: Information for the user

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 only. Do not pass it on to others. It may harm them, even if their symptoms 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 tablets are and what they are used for
2. What you need to know before you take Carbimazole tablets
3. How to take Carbimazole tablets
4. Possible side effects
5. How to store Carbimazole tablets
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1. What Carbimazole tablets are and what they are used for

The name of your medicine is Carbimazole 5 mg tablets or Carbimazole 20 mg tablets (called Carbimazole in this leaflet). This belongs to a group of medicines called 'anti-thyroid' medicines.

Carbimazole is used in adults and children **to treat 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 tablets

Do not take Carbimazole if:

- You are **allergic** to Carbimazole or any of the other ingredients of Carbimazole tablets (listed in Section 6) or to other anti-thyroid medicines such as thiamazole, methimazole or propylthiouracil
- You are **breast-feeding**
- You have a severe **liver disorder**
- You have a serious **blood disorder**.
- You had **inflammation of the pancreas** (acute pancreatitis) after taking 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'.
- You have **bone marrow depression**.
- You are receiving **radio-iodine** (for thyroid problems).
- You cannot follow the instructions for use or you cannot be monitored regularly by your doctor.

- 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.

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 Tablets

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

Pregnancy

Carbimazole can cause harm to an unborn baby. You should use reliable contraception from the time you start treatment and during treatment.

Tell your doctor if you are pregnant, think you may be pregnant or are trying to become pregnant. 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.

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.

Breast-feeding

You should not breast-feed if you are using 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 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

3. How to take Carbimazole tablets

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

How and when to take the tablets

- 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 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. 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

Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you.

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.

4. Possible side effects

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

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

- sudden rash, swelling or difficulty breathing (which may be signs of an allergic reaction)
- 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
- blistering of the skin, mouth, eyes and genitals (a serious illness known as *Stevens-Johnson syndrome*)
- swollen tongue, lips, face or throat (*angioedema*, a serious allergic reaction)
 - any of the following, which could be signs of muscle problems, jaundice or inflammation of the liver:
 - 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.

Your doctor may want you to stop taking the medicine and carry out some blood tests on you.

Other side effects (frequency not known, 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
- Kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine.

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.

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.

Do not use Carbimazole tablets after the expiry date which is stated on the blister/bottle label and outer carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Store in the original package in order to protect from moisture.

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 contains

- The active substance is carbimazole. Each tablet contains 5 mg or 20 mg of carbimazole.
- The other ingredients are lactose monohydrate, copovidone, citric acid monohydrate, croscarmellose sodium and magnesium stearate

What Carbimazole tablets looks like and contents of the pack

Carbimazole 5mg Tablets are white to off-white coloured, circular, flat beveled edge tablets, approximately 4.50 mm in size with “Y” debossed on one side and “11” on other side.

Carbimazole 20mg Tablets are white to off-white coloured, circular, flat beveled edge tablets,

approximately 7.50 mm in size with “G” debossed on one side and “111” on other side.

Carbimazole 5mg and 20mg Tablets are available in PVC/PVDC/Alu foil blister packs and HDPE bottle pack containing 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 07/2020