

Carbimazole

5mg & 20mg 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 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 tablets are and what are they used for
2. What you need to know before you take Carbimazole tablets
3. How to take Carbimazole tablets
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1. What Carbimazole tablets are and what are they used for

Carbimazole belongs to a group of medicines called anti-thyroid agents. It is used for the following:

- Hyperthyroidism, which is a condition where in the thyroid gland is hyperactive. Carbimazole is used to reduce the formation of thyroid hormones.
- Treatment in more serious cases, for example, to restore the normal function of the thyroid before its partial removal by surgery.
- It is also used together with other treatments for overactive thyroid.

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

Do not take Carbimazole tablets if you:

- are allergic to carbimazole or any of the other ingredients of this medicine (listed in section 6).
- have a serious blood disorder.
- have a severe liver disorder.
- 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 tablets if you:

- have mild or moderate liver problems.
- have swelling in your neck called an 'intra-thoracic goitre'.

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.

Tell your doctor straight away if you develop fever or abdominal pain, which may be signs of inflammation of the pancreas (acute pancreatitis). Carbimazole tablets may need to be discontinued.

Your doctor may ask you for occasional blood tests to help him determine how you are responding to treatment.

Other medicines and Carbimazole tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- Theophylline, used to treat asthma or breathing problems
- Medicines called anticoagulants, which are used to thin the blood e.g. warfarin
- Other thyroid medicines like carbimazole, thiamazole and propylthiouracil which may cause cross allergy.

Pregnancy, breast-feeding and fertility

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.

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 tablets may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

Driving and using machines

The effects of Carbimazole on the ability to drive and operate machinery have not been established. Hence do not drive or use machinery when you are on Carbimazole tablets unless you are sure your judgement and co-ordination are not affected.

Carbimazole tablets contain 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 tablets

Always take Carbimazole tablets exactly as your doctor has told you. Do not increase or decrease the dose on your own. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and elderly: The usual starting dose for adults is one to three 20mg tablets or four to twelve 5mg tablets.

Use in children: For children the usual starting dose is three 5mg tablets.

Carbimazole tablets may be taken with or without food.

Once control is achieved your doctor will gradually reduce your dose to one to three 5mg tablets each day.

You may be given an additional L-thyroxine tablet, to help control your condition. Each day's tablets may be divided into two or three daily doses.

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 him 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 temporarily.

If you have the impression that the effect of Carbimazole tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Carbimazole tablets than you should

It is important to stick to the dose on the label of the medicine. If you or someone else swallow several of these tablets all together, contact your doctor or nearest hospital emergency department immediately. Always take any tablets left over with you and also the box, as this will allow easier identification of the tablets.

If you forget to take Carbimazole tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take a double dose to make up for a forgotten dose, just carry on as before.

If you stop taking Carbimazole tablets

In order to maintain control of the thyroid gland, you may need to continue to take Carbimazole tablets for several months.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Stop taking Carbimazole tablets and tell your doctor immediately if you experience any of the following symptoms:

- 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 cough
- kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine
- 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
- Deadly skin disease (TENS or Stevens-Johnson Syndrome). Symptoms of these will include cough, aching, headaches, feverishness, red rash across the face and the trunk of the body.

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 could become life-threatening.

Tell your doctor immediately if you experience:

Carbimazole can also affect your muscles or the liver (causing jaundice and inflammation of the liver). Under medical supervision, the drug should be stopped and blood tests performed. Symptoms of these will include the following:

- muscle aches or pains
- notice yellowing of your skin or the whites of your eyes
- nerve pain
- swollen lymph nodes or swelling of the glands in your mouth
- feeling faint (low blood sugar)

The following side effects have also been reported under frequency **Not known** (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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist 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 the 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 tablets

- Keep out of the sight and reach of children.
- Do not use Carbimazole tablets after the expiry date, which is stated on the label and carton. The expiry date refers to the last day of the month.
- Store your tablets in the original container. Keep the container tightly closed. Do not store above 25°C.
- 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 contain

The name of your medicine is Carbimazole 5mg or 20mg Tablets.

The active substance in your tablet is carbimazole. Each tablet contains 5mg or 20mg of carbimazole. Other ingredients are lactose monohydrate, maize starch, citric acid monohydrate and magnesium stearate.

What Carbimazole tablets look like and contents of the pack

Carbimazole 5mg Tablets are white, round, biconvex, uncoated tablets with a score line on one side and embossed 'F1' on the other.

Carbimazole 20mg Tablets are white, round, biconvex, uncoated tablets with a score line on one side and plain on the other.

Carbimazole 5mg or 20mg Tablets are supplied in bottles of 100 tablets.

Marketing Authorisation Holder:

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Manufacturer

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