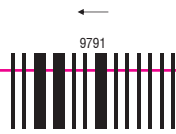


8 mm



5 mm

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 tablets or Carbimazole 20 mg tablets (it will be referred to as Carbimazole throughout the 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 other ingredients of this medicine (listed in Section 6)
- if you are allergic to other anti-thyroid medicines such as thiamazole, methimazole or propylthiouracil
- if you are breast-feeding (see section 2 "Pregnancy and breast-feeding")
- 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

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.

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 medicines).
- 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.
- If you are pregnant, think you may be pregnant or are trying to become pregnant (see section 2 "Pregnancy and breast-feeding").
- If you have mild or moderate liver problem.

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 or 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.

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.

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.

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.

Do not breast-feed if you are taking Carbimazole. This is because small amount 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 this medicine, but do not drive until you know how it affects you.

Carbimazole Tablets contain lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Carbimazole Tablets contain 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.

- Take the tablets 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 evening).

Adult 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.

Dimensions: 210 x 297 mm

Font: Times New Roman
Font size: 9 pt

Front side

CMO - ARTWORK DETAIL LABEL

		MFG. LOCATION	Celogen Generics - Daman		
PRODUCT	Carbimazole - 5mg and 20mg tablets				
BUYER/COUNTRY	SPUK	COMPONENT	Pack Insert		
DIMENSION	210 x 297 mm		PACK	----	
NEW ITEM CODE	1046692	OLD ITEM CODE	1042297		
COLOUR SHADES	Black		No. of Colours	1	
Change Control No.	Record Number: 326576		Artwork Version	2.1	
Design/Style	Front & Back Printing. To be supplied in the folded size of 60 x 50 mm.				
Substrate	40/45 GSM Paper.				
Special Instructions	Printing clarity to be clear and sharp.				
Autocartonnator Requirements	NA				
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform SCM / PD for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM SCM / PD.					

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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 taking Carbimazole tablets for several months. Your doctor will decide when your treatment can be stopped. They may ask you to have occasional blood tests to help them to determine how you are responding to the treatment.

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

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

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
- 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, 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.
- 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 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

Keep this medicine out of the sight and reach of children.

Keep the blister in the outer carton in order to protect from light.

Do not use Carbimazole after the expiry date which is stated on the label 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 tablet contains

The active substance is carbimazole. Each uncoated tablet contains 5 mg or 20 mg of carbimazole.

The other ingredients are:

- Lactose anhydrous
- Croscarmellose sodium
- Magnesium stearate

What Carbimazole tablet looks like and contents of the pack

Carbimazole 5mg Tablets: White coloured, 6.30mm round shaped, uncoated tablets, debossed "5" on one side & break line on other side.

Pack: PVC/PE/PVDC/ Aluminium foil blisters in brown coloured cartons of 10's, 20's, 28's, 30's, 50's, 56's, 100's, 112's pack sizes.

Carbimazole 20mg Tablets: White coloured, 9.60mm round shaped, uncoated tablets, debossed "20" on one side and break line on other side.

Pack: PVC/PE/PVDC/ Aluminium foil blisters in yellow coloured cartons of 10's, 20's, 28's, 30's, 50's, 56's, 100's, 112's pack sizes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, Metro Centre,
Tolpits lane, Watford,
Hertfordshire, WD18 9SS
United Kingdom

This leaflet was last revised in January 2022.



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Dimensions: 210 x 297 mm

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Font size: 9 pt

Back side

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