Package leaflet: Information for the patient

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 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 tablet is and what it is used for
- 2. What you need to know before you take carbimazole tablet
- 3. How to take carbimazole tablet
- 4. Possible side effects
- 5. How to store carbimazole tablet
- 6. Contents of the pack and other information

. What Carbimazole tablet is and what it is used for

The name of your medicine is carbimazole 5mg Tablets or carbimazole 20 mg Tablets (called carbimazole tablet in this leaflet). Carbimazole tablet contains the active substance carbimazole. Carbimazole tablet belongs to a group of medicines called anti-thyroid agents. Carbimazole tablet is used to reduce the formation of thyroid hormones in adults and children with an overactive thyroid gland. The condition is called hyperthyroidism.

Carbimazole tablet 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.

 What you need to know before you take carbimazole tablets

Do not take carbimazole tablet

- If you are allergic (hypersensitive) to carbimazole or any of the ingredients of carbimazole tablet (listed in section 6)
- If you have had a serious allergy to other antithyroid medications such as thiamazole, methimazole or propylthiouracil
- If you are 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

Talk to your doctor or pharmacist before taking carbimazole tablets

Take special care with carbimazole tablets

- 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 allergic to thiamazole, methimazole or propylthiouracil (other thyroid medications).
- If you are lactose intolerant or have any other lactose deficiency
 If you are sucrose intolerant or have any other
- sucrose deficiencyIf you are unable to comply with the instructions
- If you are unable to comply with the instructions for use or cannot be monitored regularly.
- If you are of child bearing potential
- 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 tablet

Childre

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.
- Medicine for high blood pressure called betablockers
- 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.

Your Carbimazole treatment is important for you and may need to be continued during pregnancy but very rarely it can cause harm to a developing foetus. 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.
- You should 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 Carbimazole, but do not drive until you know how it affects you.

Carbimazole tablets contains lactose

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

3. How to take carbimazole tablets

Always take Carbimazole exactly as your doctor has told you. You should 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).

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.

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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 (I-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 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 radioiodine treatment, your doctor will tell you to stop taking Carbimazole temporarily.

If you take more Carbimazole tablet 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 tablet

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.

Carbimazole 5mg tablets

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

Carbimazole 20 mg tablets

The tablet can be divided into equal doses

4. Possible side effects

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

Description	Carbimazole tablets 5 mg and 20 mg			
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If you have an allergic reaction, stop taking Carbimazole tablets 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
- itching
- 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 tablet 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.

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 lifethreatening. Your doctor should carry out tests to check for bone marrow depression before restarting your treatment.

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

Other side effects include:

- Feeling sick.
- Headache.
 - Skin rashes, including urticaria (nettle rash).
- Itching.
- Stomach upset. Painful joints.
- Hairloss.
- Loss of taste.
- 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 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 this medicine out of the sight and reach of children.

Store below 25°C. Keep the blister in the outer carton in order to protect from light

Do not use this medicine after the expiry date which is stated on the carton. 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 Tablets contains

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

What Carbimazole Tablets looks like and contents of the pack

Carbimazole 5mg tablets

White coloured, 6.30mm round shaped, uncoated tablets, debossed "5" on one side and break line on other side.

Carbimazole 20mg tablets

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

Carbimazole tablets are available in blister pack containing 7, 10, 14, 15, 20, 21, 28, 30, 40, 42, 45, 50, 56, 60, 70, 75, 80, 84, 90, 98, 100, 105, 110, 112 and 120 tablets.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for your tablet is: RIA Generics Limited, 36 Ingleby Way,

Wallington, Surrey SM69LR, UK

Manufacturer Wave Pharma Limited

4th floor, Cavendish House, 369 Burnt Oak Broadway, Edgware HA8 5AW, United Kingdom.

RIA Generics Limited

36 Ingleby Way Wallington SM69LR **United Kingdom**

If you would like to have any further information or want to report any side effects, please email at info@riagenerics.com.

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