Package leaflet: Information for the user

Carbimazole 5mg Tablets
Carbimazole 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 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 5mg Tablets or Carbimazole 20mg Tablets (referred to as Carbimazole within this leaflet). Carbimazole belongs to a group of medicines called antithyroid 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 (hypersensitive) to carbimazole or any of the other ingredients of this medicine (listed in section 6 below)
- if you are allergic to other anti-thyroid 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

Do not take Carbimazole if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

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 are of child-bearing potential
- you are allergic to thiamazole, methimazole or propylthiouracil (other thyroid medications)
- you are lactose intolerant or have any other lactose deficiency
- you are unable to comply with the instructions for use or cannot be monitored regularly
- you are pregnant, think you may be pregnant or are trying to become pregnant
- you have mild or moderate liver problems
- you develop fever or abdominal pain, which may be signs of inflammation of the pancreas (acute pancreatitis). If this happens, tell your doctor straight away. Carbimazole may need to be discontinued.

Carbimazole can cause harm to the 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 any of the above apply 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 medicines:

- 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

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Carbimazole.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice 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 this 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

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

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.

Taking this medicine

- Take the tablet by mouth with a glass of water
- The tablets can be taken before, during or after meals
- Each day's tablets may be divided into two (morning and evening) or three daily doses (morning, noon and night). Ask your doctor or pharmacist if you are unsure.

Adults and the elderly

The recommended starting dose is one to three 20mg tablets, or four to twelve 5mg tablets daily. Once control is achieved your doctor will gradually reduce your dose to one to three 5mg tablets each day.

(Continued overleaf)

Use in children and adolescents

The recommended starting dose is three 5mg tablets daily.

Carbimazole should not be used in children under 2 years of age.

The dose 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, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Carbimazole

If you forget to take a dose, 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 product, 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 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
- blistering of the skin, mouth, eyes or genitals which is a sign of a serious illness called Steven-Johnson syndrome.

In addition, if you experience any of the following symptoms **contact your doctor immediately:**

- muscle pain or weakness
- nerve pain
- swollen glands (lymph nodes)
- swollen saliva glands
- feeling faint (a sign of low blood sugar)
- yellowing of the skin or the 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.

The following side effects have been reported but the frequency is not known

- feeling sick
- stomach upset
- headache
- skin rashes including nettle rash (urticaria)
- itching
- painful joints
- hair loss
- loss of taste
- angioedema; a serious allergic reaction with symptoms that may include a swollen tongue, lips, face or throat
- inflammation of the pancreas (acute pancreatitis)
- lung problems, with 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 urine.

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.

Do not store above 25°C.

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

Do not use Carbimazole if you notice any visible signs of deterioration.

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 contains

The active substance(s) is Carbimazole. Each tablet contains 5mg or 20mg of carbimazole.

The other ingredients are lactose, lactose monohydrate, croscarmellose sodium, magnesium stearate, hypromellose and red iron oxide (E172).

What Carbimazole looks like and contents of the pack

5mg: Pale pink, round tablet with C on one side and 5 on the other side.

20mg: Pale pink, round tablet with C 20 on one side and plain on the other side.

Carbimazole is available in blisters of 20 or 100 tablets for Carbimazole 5mg Tablets and blisters of 15 or 100 tablets for Carbimazole 20mg Tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Manx Healthcare Ltd
Unit 2, Bosworth Avenue, Tournament Fields, Warwick, CV34 6UQ, UK

Other formats

To request a copy of this leaflet in Braille, large print or audio please call 01926 482511.

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MANX Healthcare

WIP URN		
APPROVED URN	✓	GCA50V-PIL-06-270125
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