

**PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### Carbimazole 5 mg Tablets Carbimazole 20 mg 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 5 mg Tablets or Carbimazole 20 mg Tablets. This will be referred to Carbimazole throughout the leaflet.

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 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 Carbimazole.

##### **Warnings and precautions**

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 medications).

- 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.
- If 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.
- 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 any of the above apply to you or you are not sure, 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**

Please 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:

- 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 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 straight away 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 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 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.

### **Carbimazole tablets contain sodium**

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

## **3. How to take Carbimazole**

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

### **Taking this medicine**

- Take this medicine by mouth. Swallow the tablets whole with a drink of water.
- You can take the tablets 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).

### **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**

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 of the use of this medicine, 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
- 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 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 life-threatening. Your doctor should carry out tests to check for bone marrow depression before restarting your treatment.

**The following side effects are reported with a not known frequency (frequency cannot be estimated from the available data):**

Other side effects include:

- 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.

### **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, website: [www.mhra.gov.uk/yellowcard](http://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.

This medicinal product does not require any special storage condition.

Do not use this medicine after the expiry date which is stated on the carton, label or blister 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 contains**

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

### **What Carbimazole looks like and contents of the pack**

Carbimazole 5 mg tablets are white coloured, 6.3 mm round shaped uncoated tablets with “5” embossed on one side and plain on other side.

Carbimazole 20 mg tablets are white coloured, 9.6 mm round shaped uncoated tablets with “20” embossed on one side and plain on other side.

Pack containing 100 tablets are available.

### **Marketing Authorisation Holder**

Mylan,  
Potters Bar,  
EN6 1TL,  
United Kingdom.

### **Manufacturer**

Viatrix UK Healthcare Limited,  
Station Close,  
Potters Bar,  
EN6 1TL,  
United Kingdom.

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