

## Package leaflet: Information for the patient

### Carbimazole 5mg, 10mg and 20mg Tablets

### Reduzol 5mg, 10mg and 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/Reduzol Tablets are and what they are used for
2. What you need to know before you take Carbimazole/Reduzol Tablets
3. How to take Carbimazole/Reduzol Tablets
4. Possible side effects
5. How to store Carbimazole/Reduzol Tablets
6. Contents of the pack and other information

#### 1. What Carbimazole/Reduzol Tablets are and what they are used for

The name of your medicine is Carbimazole/Reduzol 5mg Tablets, Carbimazole/Reduzol 10mg Tablets or Carbimazole/Reduzol 20mg Tablets (called Carbimazole/Reduzol Tablets in this leaflet). Carbimazole/Reduzol Tablets contains the active substance carbimazole. This belongs to a group of medicines called anti-thyroid agents. Carbimazole/Reduzol Tablets are used to reduce the formation of thyroid hormones in for adults and children with an over-active thyroid gland. This 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/Reduzol Tablets

##### Do not take Carbimazole/Reduzol Tablets:

- 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.
- 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

Carbimazole/**Reduzol** 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/**Reduzol** Tablets may need to be discontinued.

**Take special care with Carbimazole/**Reduzol** Tablets:**

- 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.

Talk to your doctor or pharmacist before taking Carbimazole/**Reduzol** 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 are not sure if the above applies to you, talk to your doctor or pharmacist before taking Carbimazole/**Reduzol** Tablets.

**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/**Reduzol** Tablets**

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/**Reduzol** Tablets can affect the way some medicines work. Also some medicines can affect the way Carbimazole/**Reduzol** Tablets work.

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 digoxin.
- Medicines for high blood pressure called beta-blockers.

**Pregnancy and breast-feeding**

Carbimazole/**Reduzol** 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/Reduzol Tablets may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby. 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.

Do not breast-feed if you are taking Carbimazole/Reduzol Tablets. This is because small amounts may pass into the mother's milk.

### **Driving and using machines**

You can drive when taking Carbimazole/Reduzol Tablets, but do not drive until you know how it affects you.

### **Carbimazole/Reduzol Tablets contain lactose and sodium**

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

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

## **3. How to take Carbimazole/Reduzol Tablets**

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

- The tablets should be taken by mouth.
- You can take the tablets before, during or after meals.
- Each daily dose may be divided into two (morning and evening) or three (morning, afternoon and night).

### **Adults and the elderly:**

The recommended starting dose for the 5mg tablets is between 4 and 12 tablets each day. The recommended starting dose for the 10mg tablets is between 2 and 6 tablets each day. The recommended starting dose for the 20mg tablets is between 1 and 3 tablets each day. Once control is achieved your doctor will gradually reduce your dose to one to three 5mg tablets each day.

### **Use in children**

The recommended starting dose is three 5mg 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 your dose without talking to 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/Reduzol Tablets for several months. Your doctor will decide when treatment can be stopped. Your doctor may ask you to have occasional blood tests to see 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/Reduzol Tablets temporarily.

#### **If you take more Carbimazole/Reduzol Tablets than you should**

If you take more Carbimazole/Reduzol Tablets than you should, contact your doctor or nearest hospital emergency department immediately. Take the medicine pack or any remaining tablets with you.

#### **If you forget to take Carbimazole/Reduzol Tablets**

If you forget a dose, take it as soon as you remember. If it is time for your next dose, 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, this medicine can cause side effects, although not everybody gets them.

##### **Allergic reactions**

If you have an allergic reaction, stop taking Carbimazole/Reduzol Tablets and see a doctor straight away. The signs may include: sudden rash, swelling or difficulty in breathing.

Stop taking Carbimazole/Reduzol Tablets and see a doctor straight away, if you notice any of the following side effects:

**Rare** (*may affect up to 1 in 1,000 people*):

- 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/Reduzol Tablets you should also **contact your doctor immediately**:

**Common** (*may affect up to 1 in 10 people*):

- Nerve pain.

**Side effects with unknown frequency:**

- Muscle pain or weakness,
- Swelling of lymph nodes,
- Swelling of glands in your mouth,

- Angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat,
- Feeling faint (low blood sugar).

**Very common** (*may affect more than 1 in 10 people*):

- Yellowing of your skin or white of your eyes (jaundice).

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/Reduzol Tablets until you have consulted your doctor.

Carbimazole/Reduzol Tablets can sometime 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 possible side effects are listed by frequency as follows:

**Common** (*may affect up to 1 in 10 people*):

- Headache.

**Side effects with unknown frequency:**

- Feeling sick,
- Skin rashes, including urticaria (nettle rash),
- Hair loss,
- Loss of taste,
- Itching,
- Stomach upset,
- 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,
- Painful joints.
- Inflammation of the pancreas (acute pancreatitis).

### **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/Reduzol Tablets**

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

PVC-Alu pack: Do not store above 25°C.

Alu-Alu pack (Carbimazole/Reduzol 20mg Tablets only): This medicinal product does not require any special storage conditions.

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/Reduzol Tablets contain**

The active substance is carbimazole.

Each 5mg tablet contains 5mg carbimazole.

Each 10mg tablet contains 10mg carbimazole.

Each 20mg tablet contains 20mg carbimazole.

The other ingredients are lactose monohydrate, citric acid monohydrate, croscarmellose sodium, spray aragum and magnesium stearate.

### **What Carbimazole/Reduzol Tablets look like and contents of the pack**

Carbimazole/Reduzol 5mg Tablets are white to off-white, circular, biconvex tablets debossed 'C5' on one side and plain on the other side.

Carbimazole/Reduzol 10mg Tablets are white to off-white, circular, biconvex tablets debossed 'C10' on one side and plain on the other side.

Carbimazole/Reduzol 20mg Tablets are white to off-white, circular, biconvex tablets debossed 'C20' on one side and plain on the other side.

Carbimazole/Reduzol 5mg and 10mg Tablets are available in PVC-Alu blisters.

Carbimazole/Reduzol 20mg Tablets are available in PVC-Alu or Alu-Alu blisters.

Packs containing 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100 or 112 tablets are available. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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