

PACKAGE LEAFLET: INFORMATION FOR THE USER

CARBIMAZOLE 5MG TABLETS

Carbimazole Tablets are available in two strengths: 5mg and 20mg.

Read all of this leaflet carefully before you start taking this medicine

- * 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. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Carbimazole 5mg Tablets are and what they are used for
2. Before you take Carbimazole 5mg Tablets
3. How to take Carbimazole 5mg Tablets
4. Possible side effects
5. How to store Carbimazole 5mg Tablets
6. Further information

1. What Carbimazole 5mg Tablets are and what they are used for

Carbimazole 5mg Tablets belong to a group of medicines called anti-thyroid agents. Carbimazole 5mg Tablets are used to reduce the formation of thyroid hormones in people with an overactive thyroid gland. The condition is called hyperthyroidism.

Carbimazole 5mg Tablets are 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. Before you take Carbimazole 5mg Tablets

Do not take Carbimazole 5mg Tablets

- * If you are allergic (hypersensitive) to carbimazole or any of the ingredients of Carbimazole 5mg Tablets.
- * If you are breast-feeding.
- * If you have a serious blood disorder.
- * If you have a **severe** liver disorder.

Take special care with Carbimazole 5mg Tablets

- * 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 if any of the above applies to you.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, or the following:

- * Theophylline used to treat asthma or breathing problems
- * Medicines called anticoagulants, which are used to thin the blood e.g. warfarin

Pregnancy and breast-feeding

Your Carbimazole 5mg Tablets 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 using Carbimazole 5mg Tablets.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You can drive when taking Carbimazole 5mg Tablets, but do not drive until you know how it affects you.

Important information about some of the ingredients of Carbimazole 5mg Tablets

Carbimazole 5mg Tablets contain lactose monohydrate and sucrose. 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 5mg Tablets

Always take Carbimazole 5mg Tablets 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.
- * 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 usual 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.

Children: the usual 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 the dosage without consulting your doctor first.

Do not stop taking Carbimazole 5mg Tablets until you have consulted your doctor.

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 5mg 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 5mg Tablets temporarily.

If you take more Carbimazole 5mg Tablets than you should

If you take more Carbimazole 5mg Tablets 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 5mg Tablets

If you forget to take Carbimazole 5mg Tablets 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, Carbimazole 5mg Tablets can cause side effects, although not everybody gets them.

If you experience any of these symptoms whilst taking Carbimazole 5mg Tablets **please contact your doctor immediately:**

- * 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 5mg Tablets you should also **contact your doctor immediately:**

- * muscle aches or pains
- * 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 5mg Tablets until you have consulted your doctor.

Carbimazole 5mg Tablets 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.

If at any time you are concerned about these or any other unwanted effects, **talk to your doctor as soon as possible.**

5. How to store Carbimazole 5mg Tablets

*** Keep out of the sight and reach of children.**

- * Do not use Carbimazole 5mg Tablets after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.
- * Do not store above 25°C. Store in the original container.
- * If your doctor decides to stop your treatment, take any tablets you have left back to the pharmacy.
- * If your tablets appear discoloured, or show any other signs of deterioration, take them to your pharmacist who will advise you.
- * Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. Further information

What Carbimazole 5mg Tablets contain

The active substance is carbimazole. Each tablet contains 5mg carbimazole. The tablets also contain sucrose, lactose monohydrate, acacia, talc, maize starch, magnesium stearate, gelatin and red iron oxide (E172).

What Carbimazole 5mg Tablets look like and contents of the pack

Carbimazole 5mg are pink, circular tablets with 'Neo 5' on one side and plain on the reverse.

Carbimazole 5mg Tablets come in packs of 100 tablets.

Manufacturer

Manufactured by: Amdipharm Plc, Regency House, Miles Gray Road, Basildon, Essex, SS14 3AF

or

Genexi SAS, 52 rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France.

Procured from within the EU and repackaged for the Product Licence holder: Millsdale Pharmaceuticals, Warrington, Cheshire, WA2 7UB. UK.

PL No: 08811/0038

POM

This leaflet was prepared 20th July 2013.