Package leaflet: Information for the patient

Carbimazole 5mg & 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.

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

Carbimazole belongs to a group of medicines called antithyroid agents. It is used in adults and children for the following:

- Hyperthyroidism, which is a condition where in the thyroid gland is hyperactive. Carbimazole is used to reduce the formation of thyroid hormones.
- Treatment in more serious cases, for example, to restore the normal function of the thyroid before its partial removal by surgery.
- It is also used together with other treatments for overactive thyroid.

2. What you need to know before you take Carbimazole Tablets

Do not take Carbimazole Tablets if you:

- are allergic to carbimazole or any of the other ingredients of this medicine (listed in section 6)
- have a serious blood disorder
- have a severe liver disorder
- 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 if you:

- have bone marrow depression
- have mild or moderate liver problems
- are receiving radio-iodine (for thyroid problems)
- have swelling in your neck called an 'intrathoracic goitre'
- are allergic to thiamazole, methimazole or propylthiouracil (other thyroid medication).

Carbimazole 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 Tablets may need to be discontinued.

You'r doctor may ask you for occasional blood tests to help them determine how you are responding to treatment.

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 Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- 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.

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 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. 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 Tablets 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 Tablets. 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

The effects of Carbimazole on the ability to drive and operate machinery have not been established. Do not drive or use machinery when you are on Carbimazole Tablets unless you are sure your judgement and coordination are not affected.

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.

3. How to take Carbimazole Tablets

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

- Take this medicine by mouth.
- Carbimazole Tablets may be taken with or without food.
- The tablets may be divided into two (morning and evening) or three daily doses (morning, afternoon and night).

The recommended dose is:

Adults and the elderly: The usual starting dose for adults 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.

Use in children: For children the usual starting dose is three 5mg tablets daily.

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 dose without consulting your doctor first. You may be given an additional L-thyroxine tablet, to help control your condition. Each day's tablets may be divided into two or three daily doses.

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 determine 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 Tablets temporarily.

If you have the impression that the effect of Carbimazole Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Carbimazole Tablets than you should

If you or someone else swallow several of these tablets all together, contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you.

If you forget to take Carbimazole Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take a double dose to make up for a forgotten dose, just carry on as before.

If you stop taking Carbimazole Tablets

In order to maintain control of the thyroid gland, you may need to continue to take Carbimazole Tablets for several months.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Stop taking Carbimazole Tablets and see a doctor immediately if you notice any of the following side effects:

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

 weaknéss, pale skin, rapid heartbeat, shortness of breath (pancytopenia/aplastic anaemia), easy or excessive bruising, prolonged bleeding from cuts, blood in urine or stools (thrombocytopaenia).

Very Rare (may affect up to 1 in 10,000 people):

- high temperature or fever, yellowish skin and eyes, dark coloured urine, dizziness (haemolytic anaemia)
- blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).

Not known (frequency cannot be estimated from the available data):

- sore throat, bruising or bleeding, mouth ulcers, high temperature or fever, significant tiredness, increased bruising or bleeding tendency, feeling generally unwell or think that you may have an infection (neutropenia, eosinophilia, leukopenia, agranulocytosis)
- allergic reactions: swollen tongue, lips, face or throat (angioedema), sudden rash, difficulty breathing.

Carbimazole Tablets can sometimes cause bone morrow 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.

If you experience any other side effects whilst taking Carbimazole Tablets you should **contact your doctor**. Your doctor may want you to stop taking the medicine and carry out some blood tests on you:

Not known (frequency cannot be estimated from the available data):

- feeling faint (low blood sugar)
- headache
- nerve pain, numbness or prickling sensations, sudden sharp pains or sensitivity
- bleeding, bruising
- feeling sick, stomach upset
- loss of taste
- swelling of glands in your mouth
- inflammation of the pancreas (acute pancreatitis)
- itching, skin rashes including urticaria (nettle rash)
- hair loss
- muscle pain or weakness
- high temperature, general unwellness
- swelling of lymph nodes
- yellowing of your skin or whites of your eyes (jaundice or inflammation of the liver)
- painful joints
- lung problems, e.g. shortness of breath or a cough
- kidney problems, e.g. reduction in the amount of urine passed, fluid retention, blood in the urine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 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.
- Do not use this medicine after the expiry date, which is stated on the label and carton. The expiry date refers to the last day of the month.
- Store your tablets in the original container. Keep the container tightly closed. Do not store above 25°C.
- 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 contain

The name of your medicine is Carbimazole 5mg or 20mg Tablets.

The active substance in your tablet is carbimazole. Each tablet contains 5mg or 20mg of carbimazole. Other ingredients are lactose monohydrate, maize starch, citric acid monohydrate and magnesium stearate.

What Carbimazole Tablets look like and contents of the pack

Carbimazole 5mg Tablets are white, round, biconvex, uncoated tablets with a score line on one side and embossed 'F1' on the other.

Carbimazole 20mg Tablets are white, round, biconvex, uncoated tablets with a score line on one side and plain on the other.

Carbimazole 5mg or 20mg Tablets are supplied in bottles of 100 tablets.

Marketing Authorisation Holder

Accord Healthcare Limited

Sage House, 319 Pinner Road, North Harrow, Middlesex HA1 4HF, United Kingdom

Manufacturers

Tiofarma B.V., Benjamin Franlinstraat 5-10, 3261 LW Oud-Beijerland, The Netherlands Tiofarma B.V., Hermanus Boerhaavestraat 1, 3261 ME

Oud-Beijerland, The Netherlands

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