

<p style="text-align: center;"><b>PACKAGE LEAFLET: INFORMATION FOR THE USER</b></p> <p style="text-align: center;"><b>Carbimazole 5 mg Tablets</b> <b>Carbimazole 20 mg Tablets</b></p> <p><b>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</b></p> <ul style="list-style-type: none"> <li>Keep this leaflet. You may need to read it again.</li> <li>If you have any further questions, ask your doctor or pharmacist.</li> <li>This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.</li> <li>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.</li> </ul> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p><b>What is in this leaflet</b></p> <ol style="list-style-type: none"> <li>What Carbimazole Tablets is and what it is used for</li> <li>What you need to know before you take Carbimazole Tablets</li> <li>How to take Carbimazole Tablets</li> <li>Possible side effects</li> <li>How to store Carbimazole Tablets</li> <li>Contents of the pack and other information</li> </ol> </div> <p><b>1. WHAT CARBIMAZOLE TABLETS IS AND WHAT IT IS USED FOR</b></p> <p>The name of your medicine is Carbimazole 5 mg Tablets or Carbimazole 20 mg Tablets (this will be referred to Carbimazole Tablets throughout the leaflet). This belongs to a group of medicines called anti-thyroid agents. Carbimazole Tablets are used to reduce the formation of thyroid hormones in adults and children with an overactive thyroid gland. The condition is called hyperthyroidism. Carbimazole 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.</p> <p><b>2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CARBIMAZOLE TABLETS</b></p> <p><b>Do not take Carbimazole Tablets:</b></p> <ul style="list-style-type: none"> <li>If you are allergic (hypersensitive) to carbimazole or any of the other ingredients of this medicine (listed in Section 6).</li> <li>If you are allergic (hypersensitive) to other anti-thyroid medicines such as thiamazole, methimazole or propylthiouracil.</li> <li>If you had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or thiamazole in the past.</li> <li>If you are breast-feeding.</li> <li>If you have a serious blood disorder.</li> <li>If you have a severe liver disorder.</li> </ul> <p><b>Warnings and precautions</b></p> <p>Talk to your doctor or pharmacist before taking Carbimazole Tablets</p> <ul style="list-style-type: none"> <li>If you have a swelling in your neck called an 'intrathoracic goitre'.</li> <li>If you have bone marrow depression.</li> <li>If you are receiving radio-iodine (for thyroid problems).</li> <li>If you are of child-bearing potential.</li> <li>If you are allergic to thiamazole, methimazole or propylthiouracil (other thyroid medications).</li> <li>If you are lactose intolerant or have any other lactose deficiency.</li> <li>If you are sucrose intolerant or have any other sucrose deficiency.</li> <li>If you are unable to comply with the instructions for use or cannot be monitored regularly.</li> <li>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.</li> <li>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.</li> </ul> <p>Talk to your doctor or pharmacist before taking Carbimazole Tablets</p> <ul style="list-style-type: none"> <li>If you are pregnant, think you may be pregnant or are trying to become pregnant.</li> <li>If you have mild or moderate liver problems.</li> </ul> <p><b>Children</b></p> <p>Do not give this medicine to children under the age of two years because it may not be safe or effective. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Carbimazole Tablets.</p> <p><b>Other medicines and Carbimazole Tablets</b></p> <p>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.</p> <p>This is because Carbimazole Tablets can affect the way some medicines work. Also some medicines can affect the way Carbimazole Tablets works. In particular tell your doctor or pharmacist if you are taking any of the following:</p> <ul style="list-style-type: none"> <li>Theophylline used to treat asthma or breathing problems.</li> <li>Medicines called anticoagulants, which are used to thin the blood i.e. warfarin.</li> <li>Steroids such as prednisolone.</li> <li>An antibiotic called erythromycin.</li> <li>A medicine for heart failure called digitalis.</li> <li>Medicines for high blood pressure called beta-blockers</li> </ul> <p>If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Carbimazole Tablets.</p> <p><b>Pregnancy, breastfeeding and fertility</b></p> <p>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.</p> <p>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 may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby. 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 before taking this medicine.</p> <p>Your Carbimazole 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:</p> <ul style="list-style-type: none"> <li>Your doctor should prescribe the lowest possible dose.</li> <li>Your treatment may be discontinued three to four weeks before you are due to give birth.</li> <li>You should not breast-feed if you are using Carbimazole Tablets. This is because small amounts may pass into the mother's milk.</li> </ul> <p>Ask your doctor or pharmacist for advice before taking any medicine.</p> <p><b>Driving and using machines</b></p> <p>You can drive when taking Carbimazole Tablets, but do not drive until you know how it affects you.</p> <p><b>Carbimazole Tablet contains lactose and sucrose</b></p> <p>If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.</p> <p><b>3. HOW TO TAKE CARBIMAZOLE TABLETS</b></p> <p>Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.</p> <ul style="list-style-type: none"> <li>The tablets should be taken by mouth.</li> <li>You can take the tablets before, after or during meals.</li> <li>Each day's tablets may be divided into two (morning and evening) or three daily doses (morning, noon and night).</li> </ul> <p><b>Adults and the elderly</b></p> <p>The recommended 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.</p> <p><b>Children</b></p> <p>The recommended 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.</p> <p><b>Do not</b></p> <p>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.</p>	<p>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.</p> <p>Radio-iodine is another treatment for hyperthyroidism. If you need radioiodine treatment, your doctor will tell you to stop taking Carbimazole Tablets temporarily.</p> <p><b>If you take more Carbimazole Tablets than you should</b></p> <p>If you take more Carbimazole Tablets than you should, contact your doctor or go to a hospital straight away. Take the medicine pack or this leaflet and any remaining tablets with you.</p> <p><b>If you forget to take Carbimazole Tablets</b></p> <p>If you forget to take Carbimazole Tablets take the next dose as soon as you remember. If your next dose is due, take both doses together.</p> <p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p> <p><b>4. POSSIBLE SIDE EFFECTS</b></p> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> <p><b>Allergic reactions</b></p> <p>If you have an allergic reaction, stop taking Carbimazole Tablets and see a doctor straight away. The signs may include: sudden rash, swelling or difficulty breathing.</p> <p>Stop taking Carbimazole Tablets and see a doctor straight away if you notice any of the following side effects:</p> <ul style="list-style-type: none"> <li>Sore throat</li> <li>Mouth ulcers</li> <li>High temperature or Fever</li> <li>Significant tiredness</li> <li>Increased bruising or bleeding tendency</li> <li>You are feeling generally unwell or think that you may have an infection</li> <li>Stevens-Johnson syndrome, a serious illness with blistering of the skin, mouth, eyes and genitals</li> <li>Angioedema, a serious allergic reaction with symptoms that may include swollen tongue, lips, face or throat</li> </ul> <p>In addition, if you experience any of these symptoms while taking Carbimazole Tablets you should also <b>contact your doctor immediately:</b></p> <ul style="list-style-type: none"> <li>Muscle pain or weakness</li> <li>Nerve pain</li> <li>Swelling of lymph nodes</li> <li>Swelling of glands in your mouth</li> <li>Feeling faint (low blood sugar)</li> <li>Yellowing of your skin or whites of your eyes</li> </ul> <p>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.</p> <p><b>Do not stop taking Carbimazole Tablets until you have consulted your doctor.</b></p> <p>Carbimazole 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.</p> <p><b>The following side effects are reported with a not known frequency (frequency cannot be estimated from the available data):</b></p> <p>Other side effects include:</p> <ul style="list-style-type: none"> <li>Feeling sick</li> <li>Headache</li> <li>Skin rashes, including urticaria (nettle rash)</li> <li>Itching</li> <li>Stomach upset</li> <li>Painful joints</li> <li>Hair loss</li> <li>Loss of taste</li> <li>Lung problems, with symptoms that include shortness of breath or a cough</li> <li>Kidney problems, with symptoms that include a reduction in the amount of urine passed, fluid retention and blood in the urine.</li> <li>Inflammation of the pancreas (acute pancreatitis)</li> </ul> <p>If at any time you are concerned about these or any other unwanted effects, talk to your doctor as soon as possible.</p> <p><b>Reporting of side effects</b></p> <p>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 at: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> or search for MHRA Yellow Card in the Google Play or Apple App. By reporting side effects you can help provide more information on the safety of this medicine.</p> <p><b>5. HOW TO STORE CARBIMAZOLE TABLETS</b></p> <p>Keep this medicine out of the sight and reach of children.</p> <p>Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.</p> <p>The tablets should be discarded after 100 days of the first opening of the HDPE container.</p> <p>This medicinal product does not require any special storage conditions.</p> <p>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.</p> <p><b>6. CONTENTS OF THE PACK AND OTHER INFORMATION</b></p> <p><b>What Carbimazole 5 mg and 20 mg Tablets contain</b></p> <ul style="list-style-type: none"> <li>The active substance is carbimazole. Each tablet contains 5 mg or 20 mg of carbimazole.</li> <li>The other ingredients are lactose monohydrate, microcrystalline cellulose, citric acid monohydrate, sucrose, ferric oxide (red) and magnesium stearate.</li> </ul> <p><b>What Carbimazole 5 mg and 20 mg Tablets looks like and contents of the pack</b></p> <p>Carbimazole 5 mg Tablets are Pink coloured, speckled, round, biconvex, uncoated tablets plain on both sides.</p> <p>Carbimazole 20 mg Tablets are Pink coloured, speckled, round, biconvex, uncoated tablets plain on both sides.</p> <p>Carbimazole 5 mg Tablets and Carbimazole 20 mg Tablets are available in cartons containing Aluminium-PVC/PVDC blister packs of 28's, 56's, 100's and 112's along with a leaflet inside. Not all pack sizes may be marketed.</p> <p>Carbimazole 5 mg Tablets and Carbimazole 20 mg Tablets are available in white opaque HDPE bottle with white polypropylene child resistant cap pack size: 100 tablets.</p> <p><b>Marketing Authorization Holder</b> <b>Flamingo Pharma (UK) Ltd.</b> 1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, United Kingdom.</p> <p><b>Manufacturer</b> <b>Flamingo Pharma (UK) Limited,</b> The Bloc, 38 Springfield Way, Anlaby, Hull, HU10 6RJ, United Kingdom</p> <p>This leaflet was last revised in 03/2020.</p> <p style="text-align: right;"><b>POM</b></p> <p>PL 43461/0034 PL 43461/0035</p> <p style="text-align: right;">MPLLCARXXXXTBCOM FPLXXX027V05</p>
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