Prescribing Information

Carbimazole 5mg and 20mg tablets

Presentation:
Pale pink, uncoated, round, biconvex tablets marked with LINK C5 on one side and a score-line on the reverse. Each tablet contains 5mg of carbimazole.
Pale pink, uncoated, round, biconvex tablets marked with LINK C20 on one side and a score-line on the reverse. Each tablet contains 20mg of carbimazole.
Indications: It is indicated as an anti-thyroid agent in all conditions where reduction of thyroid function like hyperthyroidism, preparation for thyroidectomy in hyperthyroidism and therapy prior to and post radio-iodine treatment.
Dosage and administration: Should only be administered once hyperthyroidism is confirmed by laboratory tests. Adult: initial dose is in the range 20mg to 60mg, taken as two to three divided doses. *Maintenance regimen:* Final dosage is usually in the range 5mg to 15mg per day. *Blocking-replacement regimen:* dosage is maintained at the initial level, i.e. 20mg to 60mg per day, and supplemental L-thyroxine, 50mcg to 150mcg per day, is administered concomitantly, in order to prevent hypothyroidism. Elderly: No special dosage regimen is required. Children: initial daily dose is 15mg per day adjusted according to response.
Contraindications: Carbimazole tablets are contraindicated in patients with a previous history of adverse reactions to carbimazole or to any of the excipients in the tablet, pre-existing haematological conditions and severe hepatic insufficiency. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Precautions and warnings: Early treatment of agranulocytosis is essential; patients should always be warned about the signs of it and should be instructed to stop the drug and to seek medical advice immediately. In such patients' white blood cell counts should be performed. Following the onset of any signs and symptoms of hepatic disorder, the drug should be stopped and liver function tests performed immediately. It should be stopped temporarily at the time of administration of radio-iodine (to avoid thyroid crisis). Regular full blood count checks should be carried out in patients who may have a poor memory. Precaution should be taken in patients with intrathoracic goitre. It use in non-pregnant women of childbearing potential should be based on individual risk/benefit assessment. There is a risk of cross-allergy between carbimazole, the active metabolite thiamazole (methimazole) and propylthiouracil.
Interactions: Particular care is required in case of concurrent administration of medication capable of inducing agranulocytosis. The serum levels of theophylline can increase and toxicity may develop.
Pregnancy and lactation: Very rare cases of congenital malformations have been observed following the use of carbimazole during pregnancy. Carbimazole is excreted in milk and if treatment is continued during lactation the patient should not continue to breast-feed her baby.
Undesirable effects: Adverse reactions usually occur in the first eight weeks of treatment. The most common minor reactions are nausea, headache, arthralgia, mild gastrointestinal disturbance, skin rashes and pruritus. Other reactions like bone marrow depression including neutropenia, eosinophilia, leucopenia, agranulocytosis, pancytopenia/aplastic anaemia, isolated thrombocytopenia, haemolytic anaemia, fever, malaise, hepatic disorders, bruising, urticarial, hair loss, myopathy, myalgia, angioedema, multi-system hypersensitivity reactions and bleeding have been reported.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: No symptoms are likely from a single large dose and so no specific treatment is indicated.
Legal Category: POM
Basic NHS Cost: *Carbimazole 5mg*: £46.50 for pack size of 100 tablets; *Carbimazole 20mg:* £114.93 for pack size of 100 tablets
Marketing Authorisation Number: PL 20072/0239; PL 20072/0240
Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL.

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Adverse events should be reported to the local regulatory authority. Reporting forms and information can be found at **http://www.mhra.gov.uk/yellowcard.** Adverse events should also be reported to **Amdipharm Mercury Medical Information** at **08700 70 30 33** or by email to **medicalinformation@amcolimited.com**