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MedChoice Pharma

# Carbimazole

# Neomerdin

**5 mg Tablet • 20 mg Tablet**

**ANTI-THYROID**

**PRODUCT DESCRIPTION:**
Carbimazole 5 mg Tablet is an orange, mottled, 8.5 mm x 5 mm, oval-shaped tablet with score on one side and plain on the other.
Carbimazole 20 mg Tablet is a yellow, mottled, 8.5 mm x 5 mm, oval-shaped tablet scored on one side and plain on the other.

**FORMULATION:**
Each tablet contains:
Carbimazole, BP ..... 5 mg
Carbimazole, BP ..... 20 mg

**CLINICAL PHARMACOLOGY:**
**Pharmacodynamics:**
Carbimazole (Neomerdin) is a pro-drug which undergoes rapid and virtually complete metabolism to the active metabolite, Thiamazole also known as Methimazole. The method of action is believed to be inhibition of the organification of iodide and the coupling of iodothyronine residues which in turn suppress the synthesis of thyroid hormones.
**Pharmacokinetics:**
Carbimazole (Neomerdin) is an anti-thyroid drug that works by blocking the production of thyroid hormone. It is rapidly absorbed from the gastrointestinal tract with peak plasma concentrations occuring about 1 to 2 hours after oral administration. Carbimazole (Neomerdin) is completely metabolized to Methimazole, the metabolite responsible for its anti-thyroid activity. Carbimazole (Neomerdin) crosses the placenta and is found in breast milk. Primary means of excretion is thru the urine. Elimination half-life may be increased in hepatic and renal impairment.

**INDICATIONS:**
Carbimazole (Neomerdin) is used in the management of hyperthyroidism, including the treatment of Graves' disease, used in the preparation of hyperthyroid patients for thyroidectomy, as an adjunct to radio-iodine therapy and treatment of thyroid storm.

**DOSAGE AND ADMINISTRATION:**
*Initial dose:* 20 mg to 60 mg daily has often been given in divided daily doses but once daily administration is also possible. Improvement is usually seen in 1 to 3 weeks and control of symptoms is achieved in 1 to 2 months.
*Typical maintenance dose:* 5 mg to 15 mg daily.
Usual Initial dose for children: 15 mg daily.
Or as prescribed by a physician.

**PRECAUTIONS:**
Patients receiving Carbimazole (Neomerdin) should be under close surveillance and should immediately seek medical help if any evidence of illness particularly mouth ulcers, sore throat, fever, bruising and malaise occurs. Full blood count should be performed. Treatment with Carbimazole (Neomerdin) should be discontinued if there is any evidence of neutropenia or liver damage. Excessive dose of anti-thyroid drugs may cause hypothyroidism and goiter.

**CONTRAINDICATION:**
Carbimazole (Neomerdin) should not be given during pregnancy and lactation.

**WARNING:**
Carbimazole (Neomerdin) can cause fetal harm when administered in the first trimester of pregnancy.

**"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph.**
**Seek medical attention immediately at first sign of any adverse drug reaction."**

**PREGNANCY AND LACTATION:**
Pregnancy: Methimazole (the metabolite of Carbimazole) has been the anti-thyroid drug most frequently involved in few reports of congenital defects following maternal use of such drugs. Infants exposed to Methimazole have been born with scalp defects (aplasia cutis congenita). Other effects include choanal atresia (an upper respiratory tract defect), esophageal atresia and tracheoesophageal fistula.

Lactation: Safety of breastfeeding during maternal treatment depends partly on the amount of Methimazole distributed into breast milk. Neonatal development and thyroid function of the infant should be closely monitored and the lowest effective dose used.

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**DRUG INTERACTIONS:**
Potassium Iodide: Iodide or iodine excess may decrease response to anti-thyroid agents.
Theophylline: Hyperthyroid patients may metabolize Theophylline more quickly than euthyroid patients. Monitor patient for Theophylline concentration and for adverse effects when starting Carbimazole (Neomerdin) therapy and until the patient is stable.
Phenindione: Concomitant administration with Carbimazole (Neomerdin) may cause excessive or subtherapeutic response to Phenindione.
Warfarin: Concomitant administration with Carbimazole (Neomerdin) may cause excessive or subtherapeutic response to Warfarin.

**ADVERSE DRUG REACTIONS:**
*Adverse effects from thiourea anti-thyroid drugs (which include Carbimazole) occur most* frequently during the first 8 weeks of treatment. The following are the reported adverse effects for the drug:

Gastrointestinal disorders: Nausea and vomiting, gastric discomfort
Skin disorders: Skin rashes, pruritus, hair loss
Nervous System disorder: Headache, taste disturbance
Blood and Lymphatic System disorders: Bone-marrow depression, mild leucopenia, aplastic anemia or isolated thrombocytopenia, hypoprothrombinemia and agranulocytosis (most serious)
Musculoskeletal and Connective Tissue disorders: Arthralgia, myopathy
Cardiovascular disorder: Vasculitis
Genito-urinary disorder: Nephritis
Immune System disorder: Lupus-like syndrome
Blood disorder: Neutropenia

**OVERDOSE AND TREATMENT:**
Excessive dose of anti-thyroid drugs may cause hypothyroidism and goiter. High doses in pregnancy may result in fetal hypothyroidism and goiter. In the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient's medical status.

**CAUTION:**
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**STORAGE CONDITION:**
Store at temperatures not exceeding 30°C.

**AVAILABILITY:**
Carbimazole 5 mg Tablet (Neomerdin)..... In blister pack of 10's (Box x 100's)
Registration No.: DR-XY36301
Date of First Authorization: October 2014

Carbimazole 20 mg Tablet (Neomerdin)..... In blister pack of 10's (Box x 100's)
Registration No.: DR-XY36391
Date of First Authorization: October 2014

Date of Revision: May 2019

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