

Methimazole

Tapdin

5 mg Tablet
ANTI-THYROID

PRODUCT DESCRIPTION:

Methimazole 5 mg Tablet (Tapdin) is a white, 8.5 x 5 mm, oval-shaped biconvex tablet with score on one side and plain on the other side.

FORMULATION:

Each Tablet contains:

Methimazole..... 5 mg

CLINICAL PHARMACOLOGY:

Pharmacodynamics:

Methimazole (Tapdin) inhibits synthesis of thyroid hormone by interfering with the incorporation of iodide into tyrosyl. Methimazole (Tapdin) also inhibits the formation of iodothyronine. As preparation for thyroidectomy, it inhibits synthesis of the thyroid hormone and causes a euthyroid state, reducing surgical problems during thyroidectomy.

Pharmacokinetics:

Methimazole (Tapdin) is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 1 to 2 hours after oral administration. The drug is concentrated in the thyroid gland and since its duration of action is more closely related to the intrathyroidal drug concentration than its plasma half-life, this results in a prolongation of its anti-thyroid activity such that single doses are possible. Methimazole (Tapdin) is not bound to plasma proteins and has an elimination half-life from plasma of about 3 to 6 hours, metabolized and excreted in the urine. Less than 12% of a dose of Methimazole (Tapdin) may be excreted as unchanged urine. *Elimination half-life may be increased in hepatic and renal impairment.* Methimazole (Tapdin) crosses the placenta and is distributed in breast milk.

INDICATIONS:

Methimazole (Tapdin) 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:

Methimazole (Tapdin) is administered orally; it is usually given in 3 equal doses at approximately 8 hours interval.

Adult: Initial dose of 15 mg to 60 mg daily, may be given in divided doses or as a single dose.

In Euthyroid patients: Usual dose is 5 mg to 15 mg daily.

Maintenance dose: 5 mg to 15 mg daily.

Children: Initial dose is 400 mcg per kg body weight daily; for maintenance, this dose may be halved.

Or as prescribed by a physician.

PRECAUTION:

Patients receiving Methimazole (Tapdin) 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 occur.

CONTRAINDICATION:

Methimazole (Tapdin) is contraindicated in the presence of hypersensitivity to the drug and in nursing mothers because the drug is excreted in milk.

WARNING:

Methimazole (Tapdin) crosses the placental membranes and 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:

Methimazole (Tapdin) should not be given during pregnancy and lactation.

Pregnancy: Methimazole (Tapdin) has been the anti-thyroid drug most frequently involved in the few reports of congenital defects following maternal use of such drugs. Infants exposed to Methimazole (Tapdin) 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 (Tapdin) distributed into breast milk. Neonatal development and thyroid function of the infant should be closely monitored.

DRUG INTERACTIONS:

Anticoagulants (oral) - The activity of anticoagulants may be potentiated by anti-vitamin K activity attributed to Methimazole (Tapdin).

Beta-adrenergic blocking agents - Hyperthyroidism may cause an increased clearance of beta blockers with a high extraction ratio. A dose reduction of beta-adrenergic blockers may be needed when hyperthyroid patients on stable digitalis glycosides may be required.

Digitalis glycosides - Serum digitalis levels may be increased when hyperthyroid patients on a stable digitalis glycoside regimen becomes euthyroid; a reduced dosage of digitalis glycosides may be required.

Theophylline - Theophylline clearance may decrease when hyperthyroid patients on a stable theophylline regimen become euthyroid; a reduced dose of theophylline may be needed.

ADVERSE DRUG REACTIONS:

Adverse effects from thiourea anti-thyroid drugs (which include Methimazole) occur most frequently during the first 8 weeks of treatment.

The following are the reported adverse effects of the drug:

Gastrointestinal disorders: Nausea and vomiting, gastric discomfort

Skin disorders: Skin rashes, pruritus, hair loss

Central Nervous System disorder: Headache

Blood and Lymphatic System disorders: Aplastic anemia or isolated thrombocytopenia and agranulocytosis (most serious)

Nervous System disorder: Taste disturbance

Musculoskeletal and connective tissue disorders: Arthralgia, myopathy

Cardiovascular disorder: Vasculitis

Genito-urinary disorder: Nephritis

Immune System disorder: Lupus-like syndrome

Treatment with Methimazole should be discontinued or withdrawn if any of the following occurs:

Blood disorder: Neutropenia

Hepatic disorder: Liver damage (usually cholestatic jaundice)

OVERDOSE AND TREATMENT:

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:

Methimazole (Tapdin) 5 mg Tablet Alu-PVC White Opaque Blister x 10's (Box x 100's)

Registration No.: DR-XY35915

Date of First Authorization: November 2014

Date of Revision: January 2019

Manufactured for:

MEDCHOICE PHARMA INC.

Unit 1001, 88 Corporate Center, Sedeño cor.
Valero Sts., Salcedo Village, Makati City

By:

SYDENHAM Laboratories, Inc.
E. Aguinaldo Highway near corner
Governor's Drive, Dasmariñas, Cavite

Methimazole

Tapdin

20 mg Tablet
ANTI-THYROID

PRODUCT DESCRIPTION:

Methimazole 20 mg Tablet (Tapdin) is a light pink, mottled, 9.5 mm round tablet, hexabeveled on one side and beveled-edge, scored on the other side.

FORMULATION:

Each Tablet contains:

Methimazole, USP 20 mg

CLINICAL PHARMACOLOGY:

Pharmacodynamics:

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Date of Revision: November 2018

Manufactured for:

MEDCHOICE ENDOCRINE GROUP, INC.

Unit 901-1001, 88 Corporate Center, Sedeño cor.

Valero St., Makati, Metro Manila

By:

SYDENHAM Laboratories, Inc.

E. Aguinaldo Highway near corner

Governor's Drive, Dasmariñas, Cavite