

# Metopride

Tablets



## Composition:

Each Metopride tablet contains:

Metoclopramide Hydrochloride equivalent to Metoclopramide 10 mg.

## Pharmacological Classification:

Dopamine receptor antagonist.

## Intended Use (Common Use of the Drug):

Treatment of gastroesophageal reflux, relief of symptoms resulting from acute and recurrent diabetic gastroparesis.

## Mechanism of Action:

- Metoclopramide stimulates motility of the upper gastrointestinal tract without stimulating gastric, biliary, or pancreatic secretions. The exact mechanism of action of metoclopramide in the treatment of gastroesophageal reflux and acute and recurrent diabetic gastroparesis has not been fully established. It seems to sensitize tissues to the action of acetylcholine. The effect of metoclopramide on motility is not dependent on intact vagal innervation, but it can be abolished by anticholinergic drugs.

- Metoclopramide increases the tone and amplitude of gastric (especially antral) contractions, relaxes the pyloric sphincter and the duodenal bulb, and increases peristalsis of the duodenum and jejunum resulting in accelerated gastric emptying and intestinal transit.

## Pharmacokinetics:

**Absorption:** Metoclopramide is well absorbed.

**Distribution:** The drug is not extensively bound to plasma proteins (about 30%). The whole-body volume of distribution is high (about 3.5 L/kg) which suggests extensive distribution of drug to the tissues.

**Metabolism:** The mean elimination half-life of metoclopramide is approximately 7 hr after administration of Metoclopramide. Metoclopramide undergoes enzymatic metabolism via oxidation as well as glucuronide and sulfate conjugation reactions in the liver.

**Excretion:** Approximately 85% of the radioactivity of an orally administered dose appears in the urine within 72 hr. Of the 85% eliminated in the urine, about half is present as free or conjugated metoclopramide.

## Indications:

- Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.

- Treatment for 4 to 12 weeks of symptomatic, documented gastroesophageal reflux in adults who fail to respond to conventional therapy.

- Relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

## Contraindications:

- This medicine is contraindicated in case of hypersensitivity to the active substance (metoclopramide) or to any of the excipients used.

- Metoclopramide is not used in patients with a history of tardive dyskinesia (TD) or dystonic reaction to metoclopramide.

- Metoclopramide is not used when stimulation of gastrointestinal motility is dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation).

- Metoclopramide is not used in patients with pheochromocytoma or other catecholamine-releasing paragangliomas. Metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to release of catecholamines from the tumor.

- Metoclopramide is not used in patients with epilepsy, may increase the frequency and severity of seizures.

## Side Effects:

- Like all medicines, this one can cause side effects, although not everyone experiences them.

- The most common adverse reactions (in approximately 10% of patients receiving 10 mg of metoclopramide four times daily) were restlessness, drowsiness, fatigue, and lassitude. In general, the incidence of adverse reactions correlated with the dosage and duration of metoclopramide administration.

- Central Nervous System Disorders: Tardive dyskinesia, acute dystonic reactions, drug-induced parkinsonism, akathisia, Convulsive seizures, Hallucinations, insomnia, headache and confusion.

- Endocrine disorders: Fluid retention secondary to transient elevation of aldosterone. Galactorrhea, amenorrhea, gynecomastia, impotence secondary to hyperprolactinemia.

- Cardiovascular Disorders: Acute congestive heart failure, possible atrioventricular block, hypotension, hypertension, supraventricular tachycardia, bradycardia, fluid retention.

- Gastrointestinal Disorders: Nausea, bowel disturbances (primarily diarrhea).

- Hepatic Disorders: Hepatotoxicity, characterized by, e.g., jaundice and altered liver function tests.

- Renal and Urinary Disorders: Urinary frequency, urinary incontinence.

- Hematologic Disorders: Agranulocytosis, neutropenia, leukopenia.

- Hypersensitivity Reactions: Bronchospasm (especially in patients with a history of asthma), urticaria, rash, angioedema.

- Eye disorders: visual disturbances.

- Metabolic disorders: porphyria.

- Inform your doctor or pharmacist if you experience any side effects not listed in this leaflet.

## Warnings & Precautions:

- **Tardive dyskinesia:** Treatment with metoclopramide can cause tardive dyskinesia (TD), a potentially irreversible and disfiguring disorder characterized by involuntary movements of the face, tongue, or extremities, especially in the elderly.

- **Extrapyramidal symptoms:** These Extrapyramidal symptoms may include involuntary movements of limbs and facial grimacing, torticollis, oculogyric crisis, rhythmic protrusion of tongue, bulbar type of speech, trismus, or dystonic reactions resembling tetanus. usually are seen during the first 24 to 48 hours of treatment with metoclopramide, occur more frequently in pediatric patients and adult patients less than 30 years of age and are even more frequent at higher doses.

- **Neuroleptic Malignant Syndrome (NMS):** Clinical manifestations of NMS include hyperthermia, muscle rigidity, altered consciousness, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac arrhythmias).

- **Depression:** Avoid using metoclopramide in patients with a history of depression, as it may worsen depression.

## Drug and Food Interactions:

- Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.

- The effects of metoclopramide on gastrointestinal motility are antagonized by anticholinergic drugs and narcotic analgesics.

- Additive sedative effects can occur when metoclopramide is given with alcohol, sedatives, hypnotics, narcotics, or tranquilizers.

- It should be used cautiously in patients receiving monoamine oxidase inhibitors.

- Absorption of drugs from the stomach may be diminished (e.g., digoxin) by metoclopramide, whereas the rate and/or extent of absorption of drugs from the small bowel may be increased (e.g., acetaminophen, tetracycline, levodopa, ethanol, cyclosporine).

- Insulin dosage or timing of dosage may require adjustment because the action of metoclopramide will hasten the movement of food to the intestines and therefore the rate of absorption.

## Pregnancy & Lactation & Fertility:

**Pregnancy:** Pregnancy Category B, Animal studies have revealed no evidence of harm to the fetus when metoclopramide is used. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Lactation:** Metoclopramide is excreted in human milk. Caution should be exercised when metoclopramide is administered to a nursing mother.

**Fertility:** Fertility: Studies in laboratory animals have revealed no evidence of impaired fertility due to metoclopramide.

## Effects on ability to drive and use machines:

Metoclopramide may cause drowsiness, dizziness, or otherwise impair the mental and/or physical abilities required for the performance of hazardous tasks such as operating machinery or driving a motor vehicle.

## Dosage and method of use:

- Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.

- Avoid treatment with Metoclopramide for longer than 12 weeks because of the increased risk of developing tardive dyskinesia with longer-term use.

- **Symptomatic Gastroesophageal Reflux Disease:** For the relief of symptomatic, documented gastroesophageal reflux disease (GERD). Administer from 10 mg to 15 mg of metoclopramide orally up to four times daily, 30 minutes before each meal and at bedtime, depending upon symptoms being treated and clinical response.

If symptoms occur only intermittently or at specific times of the day, use of metoclopramide in single doses up to 20 mg prior to the provoking situation may be preferred rather than continuous treatment. Occasionally, patients (such as elderly patients) who are more sensitive to the therapeutic or adverse effects of metoclopramide will require only 5 mg per dose.

- **Diabetic Gastroparesis (Diabetic Gastric Stasis):** For the relief of symptoms associated with diabetic gastroparesis (diabetic gastric stasis), therapy of two to eight weeks is recommended. Therapy should not exceed 12 weeks in duration. Administer 10 mg of metoclopramide 30 minutes before each meal and at bedtime for two to eight weeks, depending upon response and the likelihood of continued well-being upon drug discontinuation. The initial route of administration should be determined by the severity of the presenting symptoms. If only the earliest manifestations of diabetic gastric stasis are present, oral administration of metoclopramide may be initiated. However, if severe symptoms are present, therapy should begin with metoclopramide injection.

## Renal Insufficiency:

Renally impaired patients whose creatinine clearance is below 40 mL/min may be more sensitive to the therapeutic dose or the adverse effects of metoclopramide. Therefore, these patients should start therapy at a lower dose (approximately half the recommended dosage).

- **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

- **Geriatric Use:** The risk of developing Parkinson's-like side effects increases with ascending dose and the risk of toxic reactions to this drug may be greater in patients with impaired renal function., so the dose of metoclopramide should be adjusted or discontinued. Inform your doctor or pharmacist if you forget take medicine and before stopping its use.

## Overdoses and Toxicity and methods of treatment:

**Symptoms:** Symptoms: Symptoms of overdosage may include drowsiness, disorientation and extrapyramidal reactions. Symptoms are self-limiting and may disappear within 24 hours.

**Treatment:** Anticholinergic or antiparkinson drugs or antihistamines with anticholinergic properties may be helpful in controlling the extrapyramidal reactions. Hemodialysis removes relatively little metoclopramide, probably because of the small amount of the drug in blood relative to tissues.

## Physical Properties:

White, Round, Scored Tablets.

## Storage Conditions:

Store at a temperature below 30° C.

Keep out of reach of children.

## PACKAGE:

Each Metopride tablets carton box contains 20 film-coated tablets in 2 blister strips.

