

Composition

Each Tablet contains:

Metoclopramide HCl 10 mg

Each 5 ml syrup contains:

Metoclopramide HCl 5 mg

Each 2 ml ampoule contains:

Metoclopramide HCl 10 mg

Each 1 ml oral drops contains:

Metoclopramide HCl 2 mg

Each Pediatric supp. contains:

Metoclopramide 10 mg

Each Adults supp. contains:

Metoclopramide 20 mg

Indications & Usage

Antiemetic:

- Nausea and vomiting, particularly in gastro-intestinal disorders and treatment with cytotoxic or radiotherapy, migraine.
- To speed up the transit of barium during intestinal follow-through the examination.
- As an accessory treatment for gastro-oesophageal reflux disease.
- In post-operative nausea and vomiting
- In cytotoxic-induced nausea and vomiting.

Contra-indications

Gastro-intestinal obstruction, perforation or hemorrhage, 3-4 days after gastro-intestinal surgery, pheochromocytoma and breast-feeding.

Side-effects

Extrapyramidal effects (especially in children and young adults), Hyperprolactinaemia, occasionally, tardive dyskinesia on prolonged administration; also reported, drowsiness, restlessness, diarrhoea, depression, neuroleptic malignant syndrome, rashes, pruritus, oedema; cardiac conduction abnormalities reported following intravenous administration, rarely methaemoglobinaemia (more severe in G6PD deficiency).

Drug Interactions

1. The effects of Metoclopramide on GIT 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.

2. The finding that Metoclopramide release catecholamines in patients with essential hypertension

suggested that it should be used cautiously, if at all, in patients receiving monoamine oxidase inhibitors.

3. Absorption of drugs from 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, Cyclosporin).

4. Gastroparesis (gastric stasis) may be responsible for poor diabetic control in some patients exogenously administered insulin may begin to act before food has left the stomach and lead to hypoglycemia, because the action of metoclopramide will influence the delivery of food to the intestine and thus the rate of absorption, insulin dosage or timing of dosage may require adjustment.

Warnings & Precautions

- Hepatic and renal impairment.
- Elderly, young adults, and children may mask underlying disorders as cerebral irritation.
- Epilepsy, Pregnancy, Porphyrin.

Mental depression has occurred in patients with or without prior history of depression Symptoms have ranged from mild to severe and have include suicidal ideation and suicide. Metoclopramide should be given to patients with a prior history of depression only if the expected benefits outweigh the potential risks.

Extra-pyramidal symptoms manifested primarily as acute dystonic reaction occur in approximately 500 patients treated with the usual adult dosage of 30 - 40 mg/day of Metoclopramide, these 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.

Parkinsonian-like symptoms have occurred more commonly within the first 6 months after beginning treatment with Metoclopramide. Patient with pre-existing parkinsonian's disease should be given Metoclopramide cautiously.

Tardive Dyskinesia: A syndrome consisting of potentially irreversible involuntary, dyskinetic movements may develop in patients treated with Metoclopramide.

Dosage & administration

As directed by the physician or as follows:

By mouth (Tablets - Drops - Syrup) or by intramuscular injection (I.M.) or by intravenous (I.V.) injection near 1 - 2 minutes (ampoules) or by using Suppositories.

Adults: 10 mg (1 tablet or 1 ampoule) 1 - 3 times daily according to the patients case.

Young adults 15 - 19 years under 60 kg: 5 mg (tablet or ampoule) 3 times daily.

Children:

- up to 1 year (up to 10 kg): 1 mg (10 drops) twice daily,
- 1 - 3 years (10 - 14 kg): 1 mg (10 drops) 2-3 times daily,
- 3 - 5 years (15 - 19 kg): 2 mg (20 drops or teaspoonful of syrup) 2 - 3 times daily,
- 5 - 9 years (20 - 29 kg): 2mg (teaspoonful or syrup) 3 times daily,
- 9 - 14 years (30 kg and over): 5 mg (1 teaspoonful of syrup) 3 times daily.

For diagnostic procedures: as a single dose 5 - 10 minutes before examination.

Adults 10 - 20 mg (1 tablet - 2 tablets or 1 adult suppository).

Young adults 15 - 19 years: 10 mg (1 pediatric suppository or 1 tablet).

Children:

- under 3 years: 1 mg (about 10 drops),
- 3 - 9 years: 2 mg (20 drops or teaspoonful of syrup),
- 9 - 14 years: 5 mg (1 teaspoonful of syrup or tablet or ampoule).

Note: Daily dose of metoclopramide shouldn't normally exceed 500 µg/Kg particularly for children and young adult (restricted use).

Storage

Store in temperature not exceeding 25°C. Protect from light.

Keep out of reach of children.

Packing

Pack contains 2 or 100 strips 10 tablets (Meclopram tablets).

Pack contains 5, 50 or 100 ampoules 2 ml (Meclopram ampoules).

Pack contains bottle of 120 ml (Meclopram syrup).

Pack contains dropper bottle of 10 ml (Meclopram oral drops).

Pack contains 5 suppositories (Meclopram pediatric Supp).

Pack contains 5 suppositories (Meclopram adult Supp).

Company

Produced by: Alexandria Co. for Pharmaceuticals - Alexandria - A.R.E.