METORAM

Metoclopramide Hydroch

Injectable solution, Ampoules

Composition

Each 2 ml ampoule contains:

Active ingredient: Metoclopramide hydrochloride 10 mg.

Excipients: Sodium chloride, sodium metabisulphite, benzyl alcohol, water for injection.

Properties

The active ingredient of **Metoram**, metoclopramide, stimulates motility of the upper gastrointestinal tract without stimulating gastric, biliary, or pancreatic secretions. Metoclopramide increases the tone and amplitude of gastric contractions, relaxes pyloric sphincter, and increases peristalsis of the small intestine resulting in accelerated gastric emptying. Metoclopramide exerts its effect on the upper gastrointestinal tract by inhibiting smooth muscle relaxation produced by dopamine, thus enhancing cholinergic response. Dopamine antagonism within the chemoreceptor trigger zone may also contribute to the antiemetic activity of metoclopramide.

Indications

Metoram is indicated for:

- Nausea and vomiting, particularly in gastrointestinal disorders, to provide symptomatic relief.
- The prevention of nausea and vomiting associated with emetogenic cancer chemotherapy or radiotherapy.
- The prevention of postoperative nausea and vomiting.
- Gastroesophageal reflux disease in adults, for the treatment of heartburn and delayed gastric emptying.
- Diabetic gastroparesis, for the relief of acute and recurrent symptoms.
- Digestive dyskinesia, to correct slow gastric emptying.
- To facilitate small bowel intubation procedures.
- To stimulate gastric emptying during radiographic examinations of gastrointestinal tract.

Dosage and administration

Adults:

- Delayed gastrointestinal emptying or as peristaltic stimulant (intestinal intubation), 10 mg as a single dose by intravenous injection.
- For the prevention of nausea in cancer chemotherapy, intravenous infusion, 2 mg/kg of body weight, administered 30 minutes before the chemotherapeutic agent and may be repeated as needed every 2 or 3 hours.
- For prevention of postoperative emesis, 10-20 mg to be administered intramuscularly near the end of surgery.
- For diagnostic procedures, a single dose of 10-20 mg is administered 5-10 minutes before examination.

Intravenous injection is made slowly over a 1 to 2 minutes period while intravenous infusion should be made over a period of not less than 15 minutes.

Children:

The usual daily dose is 0.1-0.3 mg/kg/day.

Contraindications

Metoram is contraindicated in patients known to be hypersensitive to metoclopramide or any other ingredient in the product. Metoclopramide is contraindicated in patients with epilepsy as well as in those having gastrointestinal bleeding, mechanical obstruction, or perforation. It should be avoided 3 - 4 days following gastrointestinal surgery.

Metoclopramide should not be prescribed for patients with phaeochromocytoma as it may precipitate acute hypertensive response. Metoclopramide is contraindicated in combination with antiparkinsonian drugs (levodopa, dopamine agonists) and selegiline.

Precautions

Metoram should be given cautiously to patients affected by asthma, hypertension, Parkinson's disease, or porphyria.

Caution is also recommended with the use of **Metoram** in elderly, young adults, and children; accurate measurement of the dose is recommended.

The use of **Metoram** may mask the clinical picture of underlying disorders such as cerebral irritation.

Metoram ampoules contain sodium metabisulphite as an excipient. Rarely, some susceptible patients may be hypersensitive to this substance and may develop allergic-type reactions. If any signs of hypersensitivity reactions occur, treatment should be immediately discontinued.

Hepatic impairment: Dosage reduction may be required in patients with hepatic impairment.

Renal impairment: In patients with severe renal impairment, **Metoram** should be avoided or otherwise used in small doses due to increased risk of extrapyramidal reactions.

Pregnancy: Although metoclopramide is not known to be harmful during pregnancy, it should be used only when clearly needed.

Lactation: Metoclopramide is excreted in breast milk in small amounts; however, its use during lactation is better to be avoided unless considered essential.

Side effects

Use of **Metoram** may lead to drowsiness and restlessness. Extrapyramidal symptoms may occur less frequently, especially in children and young adults.

Occasionally, on prolonged administration, tardive dyskinesia and hypoprolactinaemia may be experienced.

Only rarely; depression, diarrhea, and neuroleptic malignant syndrome have been reported.

Following intravenous administration, hypotension and cardiac conduction abnormalities have been rarely reported.

Overdosage

As there is no specific antidote for overdosing with metoclopramide, the treatment should be symptomatic. Anticholinergic or antiparkinson drugs or antihistamine with anticholinergic properties are given to help in controlling the extrapyramidal reactions.

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Drug interactions

Upon concurrent administration, metoclopramide may increase the absorption of aspirin and paracetamol, thereby resulting in enhanced effects.

The effect of metoclopramide on gastrointestinal activity may be antagonised upon concurrent administration with opioid analgesics or antimuscarinics.

The concurrent administration of metoclopramide with antipsychotics, lithium, or tetrabenazine may increase the risk of extrapyramidal effects.

Upon concurrent administration, metoclopramide may interact with dopaminergic agents as follows:

- Antagonises hypoprolactinaemic effect of bromocriptine.
- Increases plasma concentration of levodopa.
- Antagonises antiparkinsonian effects of pergolide.

Presentation

Metoram injectable solution is available in packs of 5 or 50 ampoules of 2 ml.

Storage conditions

Store below 30˚C. Protect from light and heat.

ARWAN Pharmaceutical Industries Lebanon s.a.l., Jadra, Lebanon

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists