

METORAM Metoclopramide Hydroch

ution, Ampoule

Composition

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Each 2 ml ampoule contains:

Active ingredient: Metoclopramide hydrochloride 10 mg.

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

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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

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- Metoram is indicated for
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 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
- the treatmone emptying.
 Diabetic gastroparesis recurrent symptoms.
 Pinestive dyskinesia,
- esis, for the relief of acute and recurrent - Digestive to correct slow gastric
- Digestive dysalicosa, -emptying.

 To facilitate small bowel intubation procedures.

 To stimulate gastric emptying during radiographic examinations of gastrointestinal tract.

- Dosage and administration
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 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

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Metoram is contraindicated in patients known be hypersensitive to metoclopramide or any of ingredient in the product. Metoclopramide is nontraindicated in patients with epilepsy as well as in those having gastrointestinal bleeding, mechani-al obstruction, or perforation. It should be avoided

cal 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. Metoclo-pramide is contraindicated in combination with antiparkinsonian drugs (levodopa, dopamine agonists) and selegiline.

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Precautions

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

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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 he harmful divine commended.

risk of extrapyramical 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

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experienced.
Only rarely; depression, diarrhea, and neuroleptic malignant syndrome have been reported.
Following intravenous administration, hypotension and cardiac conduction abnormalities have been rarely reported.

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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

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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

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

 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