

Metoclopramide Injection BP

For IM / IV use only

COMPOSITION

Each ml contains		
Metoclopramide Hydrochloride	BP	
Eq. to anhydrous Metoclopramide Hydrochloride		5mg
Benzyl Alcohol	BP	2% v/v
(As Preservative)		

PHARMACOLOGICAL CLASS : Antiemetic agent

Metoclopramide has antiemetic, anti-nauseant and gastrokinetic activity. It stimulates motility of the upper gastrointestinal tract without stimulating gastric, biliary or pancreatic secretions. The rate of gastric emptying is increased due to increased peristalsis of the jejunum and duodenum. The tone and amplitude of gastric contractions are increased, with relaxation of the pyloric sphincter and duodenal bulb. These effects combine to result in decreased intestinal transit time. The effect of metoclopramide on motility is not dependent on intact vagal innervation, but it can be abolished by anticholinergic drugs. Metoclopramide has little, if any, effect on the motility of the colon or bladder. Metoclopramide also exhibits dopamine antagonist activity and consequently produces sedation and, rarely, other extrapyramidal reactions. It may have serotonin receptor (5HT₃) antagonist properties. Metoclopramide inhibits the central and peripheral effects of apomorphine, induces release of prolactin and produces a transient increase in circulating aldosterone levels

INDICATION:

Adults (20 years and over)

Digestive disorders: Metoclopramide Injection restores normal co-ordination and tone to the upper digestive tract. Metoclopramide Injection relieves the symptoms of gastro-duodenal dysfunction including: Dyspepsia, Heartburn, Flatulence, Sickness, Regurgitation of bile, Pain. These symptoms may be associated with such conditions as: Peptic ulcer, Duodenitis, Reflux oesophagitis, Hiatus hernia, Gastritis, Cholelithiasis and Post-cholecystectomy dyspepsia

Nausea and vomiting: Metoclopramide Injection is indicated for the treatment of the nausea and vomiting associated with: Gastro-intestinal disorders, Cyclical vomiting, Intolerance to cytotoxic drugs, Congestive heart failure, Deep x-ray or cobalt therapy, Post-anaesthetic vomiting

Migraine: Metoclopramide Injection relieves symptoms of nausea and vomiting, and overcomes gastric stasis associated with attacks of migraine. This improvement in gastric emptying assists the absorption of concurrently administered oral anti-migraine therapy (e.g. paracetamol) which may otherwise be impaired in such patients.

Diagnostic procedures: Radiology, Duodenal intubation, Metoclopramide Injection speeds up the passage of a barium meal by decreasing gastric emptying time, co-ordinating peristalsis and dilating the duodenal bulb. Metoclopramide Injection also facilitates duodenal intubation procedures.

Young adults and children

The use of Metoclopramide Injection in patients under 20 years should be restricted to the following:

Severe intractable vomiting of known cause, vomiting associated with radiotherapy and intolerance to cytotoxic drugs, as an aid to gastro-intestinal intubation, and as part of the premedication before surgical procedures.

CONTRAINDICATION :

Metoclopramide Injection should not be used in patients with pheochromocytoma, should not be used during the first three to four days following operations such as pyloroplasty or gut anastomosis as vigorous muscular contractions may not help healing, Gastrointestinal obstruction, perforation or haemorrhage.

Pharmacokinetic properties : Metoclopramide is metabolised in the liver and the predominant route of elimination of metoclopramide and its metabolites is via the kidney.

DOSAGE :

As directed by the Physician

UNDESIRABLE EFFECTS :

Various extrapyramidal reactions to Metoclopramide Injection, usually of the dystonic type, have been reported. The incidence of dystonic reactions, particularly in children and young adults, is increased if daily dosages higher than 0.5mg per kg body weight are administered. Dystonic reactions include: spasm of the facial muscles,

trismus, rhythmic protrusion of the tongue, a bulbar type of speech, spasm of extra-ocular muscles including oculogyric crises, unnatural positioning of the head and shoulders and opisthotonos.

Very rare occurrences of the neuroleptic malignant syndrome have been reported. This syndrome is potentially fatal and comprises hyperpyrexia, altered consciousness, muscle rigidity, autonomic instability and elevated levels of creatine phosphokinase (CPK) and must be treated urgently (recognised treatments include dantrolene and bromocriptine). Metoclopramide should be stopped immediately if this syndrome occurs. There have been very rare reports of abnormalities of cardiac conduction (such as bradycardia and heart block) in association with intravenous metoclopramide. Tardive dyskinesia has been reported during prolonged treatment in a small number of mainly elderly patients. Patients on prolonged treatment should be regularly reviewed. Rarely, drowsiness, restlessness, confusion, anxiety and diarrhoea have been reported in patients receiving metoclopramide therapy. Depression has been reported extremely rarely.

Raised serum prolactin levels have been observed during metoclopramide therapy: this may result in galactorrhoea, irregular periods and gynaecomastia.

OVERDOSE & TREATMENTS :

In cases of overdosage, acute dystonic reactions have occurred. Very rarely AV block has been observed. Should treatment of a dystonic reaction be required, an anticholinergic anti-Parkinsonian drug or a benzodiazepine may be used.

WARNING & PRECAUTION :

Precautions: If vomiting persists the patient should be reassessed to exclude the possibility of an underlying disorder e.g. cerebral irritation.

Care should be exercised in epileptic patients and patients being treated with other centrally acting drugs.

Special care should be taken in cases of severe renal and hepatic insufficiency Metoclopramide Injection should be used with care in association with other drugs acting at central dopamine receptors, such as levodopa, bromocriptine and pergolide.

Metoclopramide Injection may reduce plasma concentrations of atovaquone.

Pregnancy and lactation :

Animal tests in several mammalian species and clinical experience have not indicated a teratogenic effect. Nevertheless Metoclopramide Injection should only be used when there are compelling reasons and is not advised during the first trimester.

During lactation metoclopramide is found in breast milk, therefore it should not be used during lactation. Keep out of reach of children.

STORAGE CONDITION : Store below 30°C. Protect from light.

PRESENTATION : 2ml Ampoules



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