ANISONS

Metoclopramide Injection BP

10mg/2ml

For I.M. / I.V. Use

Composition:
Each 2 ml contains:
Metoclopramide Hydrochloride BP
Eq. to Anhydrous Metoclopramide Hydrochloride...10 mg
Water for Injection BP.....q.s.

Pharmacodynamic properties
Pharmacotherapeutic group: Agents stimulating gastro-intestinal motility
ATC code: A03FA01
Mechanism of action
The action of metoclopramide is closely associated with parasympathetic nervous control of the upper gastro-intestinal tract, where it has the effect of encouraging normal peristaltic action. This provides for a fundamental approach to the control of those conditions where disturbed gastro-intestinal motility is a common underlying factor.
Metoclopramide stimulates activity of the upper gastro-intestinal tract and restores normal co-ordination and tone. Gastric emptying is accelerated and the resting tone of the gastrooesophageal sphincter is increased. Metoclopramide is a dopamine-receptor antagonist with a direct anti-emetic effect on the medullary chemoreceptor trigger zone.

Pharmacokinetic properties
Absorption:
Metoclopramide is rapidly absorbed from the gastrointestinal tract and undergoes variable first-pass metabolism in the liver.
Biotransformation and Elimination:
Metoclopramide is metabolised in the liver and the predominant route of elimination of metoclopramide and its metabolites is via the kidney. It crosses the placenta and is excreted in breast milk. The elimination half-life is about 6 hours.
Renal impairment:
The clearance of metoclopramide is reduced by up to 70% in patients with severe renal impairment, while the plasma elimination half-life is increased (approximately 10 hours for a creatinine clearance of 10-50 mL/minute and 15 hours for a creatinine clearance <10 mL/minute).
Hepatic impairment:
In patients with cirrhosis of the liver, accumulation of metoclopramide has been observed, associated with a 50% reduction in plasma clearance.

Therapeutic indications
Paediatric population:
- Metoclopramide 10mg/2ml Injection is indicated in children (1 – 18 years) for:
- Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second line option
- Treatment of established post-operative nausea and vomiting (PONV) as a second line option
- For other indications, the use in the paediatric population is not recommended.

Adult population:
- Metoclopramide 10mg/2ml Injection is indicated in adults for:
- Prevention of post-operative nausea and vomiting (PONV)
- Symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting
- Prevention of radiotherapy induced nausea and vomiting (RINV)

Posology and method of administration
The solution can be administered intravenously or intramuscularly.
Intravenous doses should be administered as a slow bolus (at least over 3 minutes).
All indications (paediatric patients aged 1-18 years)
The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to three times daily by intravenous route. The maximum dose in 24 hours is 0.5 mg/kg body weight.
A minimal interval of 6 hours between two administrations is to be respected, even in case of vomiting or rejection of the dose.
The maximum treatment duration is 48 hours for treatment of established post-operative nausea and vomiting (PONV).
The maximum treatment duration is 5 days for prevention of delayed chemotherapy induced nausea and vomiting (CINV).
All indications (adult patients)
or prevention of PONV a single dose of 10mg is recommended. For the symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting and for the prevention of radiotherapy induced nausea and vomiting (RINV): the recommended single dose is 10 mg, repeated up to three times daily
The maximum recommended daily dose is 30 mg or 0.5mg/kg body weight.
The injectable treatment duration should be as short as possible and transfer to oral or rectal treatment should be made as soon as possible.
The maximum recommended treatment duration is 5 days.

Special population
Elderly: In elderly patients a dose reduction should be considered, based on renal and hepatic function and overall frailty.
Renal impairment: In patients with end stage renal disease (Creatinine clearance ≤ 15 ml/min), the daily dose should be reduced by 75%. In patients with moderate to severe renal impairment (Creatinine clearance 15-60 ml/min), the dose should be reduced by 50%.
Hepatic impairment: In patients with severe hepatic impairment, the dose should be reduced by 50%.
Paediatric population: Metoclopramide is contraindicated in children aged less than 1 year.

Contraindications
- Hypersensitivity to the active substance
- Gastrointestinal haemorrhage, mechanical obstruction or gastro-intestinal perforation for which the stimulation of gastrointestinal motility constitutes a risk
- Confirmed or suspected phaeochromocytoma, due to the risk of severe hypertension episodes
- History of neuroleptic or metoclopramide-induced tardive dyskinesia
- Epilepsy (increased crises frequency and intensity)
- Parkinson's disease
- Combination with levodopa or dopaminergic agonists
- Known history of methaemoglobinaemia with metoclopramide or of NADH cytochrome-b5 deficiency.
- Use in children less than 1 year of age due to an increased risk of extrapyramidal disorders
- Metoclopramide 10mg/2ml Injection 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
- Metoclopramide should not be used during breast-feeding

Fertility, pregnancy and lactation
Pregnancy
A large amount of data on pregnant women (more than 1000 exposed outcomes) indicates no malformative toxicity nor foetotoxicity. Metoclopramide can be used during pregnancy if clinically needed. Due to pharmacological properties (as other neuroleptics), in case of metoclopramide administration at the end of pregnancy, extrapyramidal syndrome in the newborn cannot be excluded. Metoclopramide should be avoided at the end of pregnancy. If metoclopramide is used, neonatal monitoring should be undertaken.
Breastfeeding
Metoclopramide is excreted in breast milk at a low level. Adverse reactions in the breast-fed baby cannot be excluded. Therefore metoclopramide is not recommended during breastfeeding. Discontinuation of metoclopramide in breastfeeding women should be considered.

Overdose
Symptoms
Extrapyramidal disorders, drowsiness, a decreased level of consciousness, confusion, hallucination and cardio-respiratory arrest may occur.
Management
In case of extrapyramidal symptoms related or not to overdose, the treatment is only symptomatic (benzodiazepines in children and/or anticholinergic anti-parkinsonian medicinal products in adults).
A symptomatic treatment and a continuous monitoring of the cardiovascular and respiratory functions should be carried out according to clinical status.

Storage:
Store below 30°C. Protect from light.

Keep the medicine out of reach of children.

Presentation: A pack of 5 x 2 ml Ampoules

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