AVENACY

Metoclopramide

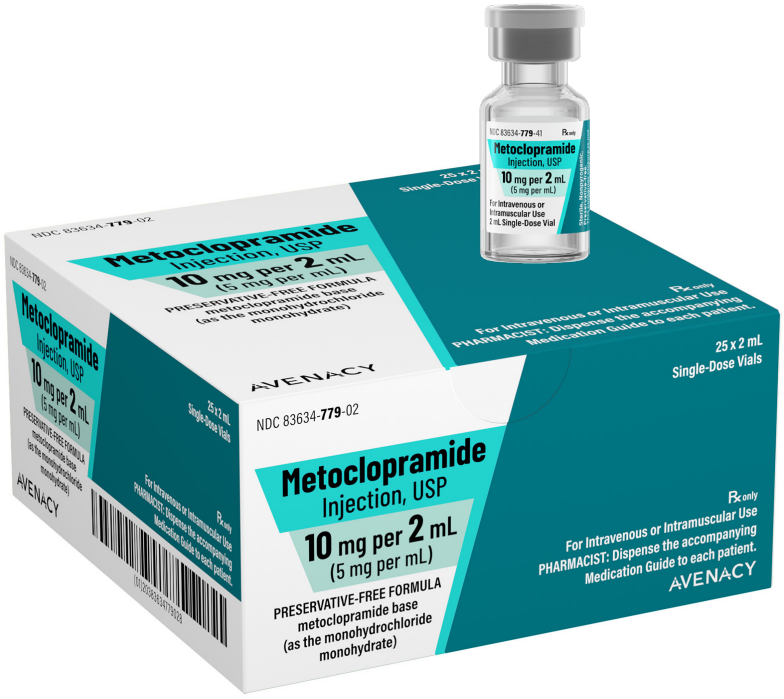
Injection, USP

10 mg

NDC 83634-779-02
10 mg per 2 mL

DESCRIPTION	Single-Dose Vial
CONCENTRATION	5 mg per mL
CLOSURE	13 mm
UNIT OF SALE	25 Vials
BAR CODED	Yes
STORAGE	Room Temp.

• AP RATED • PRESERVATIVE-FREE •
• NOT MADE WITH NATURAL RUBBER LATEX •



PLEASE SEE IMPORTANT SAFETY INFORMATION ATTACHED, INCLUDING BOXED WARNING.
VISIT WWW.AVENACY.COM/PRODUCTS/METOCLOPRAMIDE-INJECTION-USP FOR FULL PRESCRIBING INFORMATION.

ORDER THROUGH YOUR WHOLESALER:

STRENGTH	Cardinal	Cencora/ABC	McKesson	Morris & Dickson
10 mg per 2 mL	5942644	10292650	2982205	435529

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METOCLOPRAMIDE Injection, USP

INDICATIONS AND USAGE

- **Diabetic Gastroparesis (Diabetic Gastric Stasis).** Metoclopramide Injection, USP (metoclopramide hydrochloride, USP) is indicated for the relief of symptoms associated with acute and recurrent diabetic gastric stasis.
- **The Prevention of Nausea and Vomiting Associated with Emetogenic Cancer Chemotherapy.** Metoclopramide Injection, USP is indicated for the prophylaxis of vomiting associated with emetogenic cancer chemotherapy.
- **The Prevention of Postoperative Nausea and Vomiting.** Metoclopramide Injection, USP is indicated for the prophylaxis of postoperative nausea and vomiting in those circumstances where nasogastric suction is undesirable.
- **Small Bowel Intubation.** Metoclopramide Injection, USP may be used to facilitate small bowel intubation in adults and pediatric patients in whom the tube does not pass the pylorus with conventional maneuvers.
- **Radiological Examination.** Metoclopramide Injection, USP may be used to stimulate gastric emptying and intestinal transit of barium in cases where delayed emptying interferes with radiological examination of the stomach and/or small intestine.

IMPORTANT SAFETY INFORMATION

WARNING: TARDIVE DYSKINESIA

Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.

Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.

Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia

CONTRAINDICATIONS

- Metoclopramide should not be used whenever stimulation of gastrointestinal motility might be dangerous, e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation.
- Metoclopramide is contraindicated in patients with pheochromocytoma because the drug may cause a hypertensive crisis, probably due to release of catecholamines from the tumor. Such hypertensive crises may be controlled by phentolamine.
- Metoclopramide is contraindicated in patients with known sensitivity or intolerance to the drug.
- Metoclopramide should not be used in epileptics or patients receiving other drugs which are likely to cause extrapyramidal reactions, since the frequency and severity of seizures or extrapyramidal reactions may be increased.

WARNINGS

- **Neuroleptic Malignant Syndrome (NMS).** There have been rare reports of an uncommon but potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) associated with metoclopramide.
- **Extrapyramidal Symptoms (EPS).** Acute Dystonic Reactions occur in approximately 1 in 500 patients treated with the usual adult dosages of 30 to 40 mg/day of metoclopramide. These usually are seen during the first 24 to 48 hours of treatment with metoclopramide, occur more frequently in pediatric patients and adult patients less than 30 years of age. Treatment with metoclopramide can cause tardive dyskinesia (TD), a potentially irreversible and disfiguring disorder characterized by involuntary movements of the face, tongue, or extremities. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. Parkinsonian-like Symptoms, including bradykinesia, tremor, cogwheel rigidity, or mask-like facies, have occurred more commonly within the first 6 months after beginning treatment with metoclopramide, but occasionally after longer periods. These symptoms generally subside within 2 to 3 months following discontinuance of metoclopramide. Mental depression has occurred in patients with and without prior history of depression. Symptoms have ranged from mild to severe and have included 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.

PRECAUTIONS

- Caution should be exercised when metoclopramide is used in patients with hypertension.
- Intravenous injections of undiluted metoclopramide should be made slowly allowing 1 to 2 minutes for 10 mg since a transient but intense feeling of anxiety and restlessness, followed by drowsiness, may occur with rapid administration.
- Metoclopramide produces a transient increase in plasma aldosterone, certain patients, especially those with cirrhosis or congestive heart failure, may be at risk of developing fluid retention and volume overload. If these side effects occur at any time during metoclopramide therapy, the drug should be discontinued.
- Intravenous administration of metoclopramide injection diluted in a parenteral solution should be made slowly over a period of not less than 15 minutes.
- Giving a promotility drug such as metoclopramide theoretically could put increased pressure on suture lines following a gut anastomosis or closure.

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ADVERSE REACTIONS

The incidence of adverse reactions correlates with the dose and duration of metoclopramide administration. The following reactions have been reported, although in most instances, data do not permit an estimate of frequency. Restlessness, drowsiness, fatigue, and lassitude may occur in patients receiving the recommended prescribed dosage of metoclopramide injection. Acute dystonic reactions, the most common type of EPS associated with metoclopramide, occur in approximately 0.2% of patients (1 in 500) treated with 30 to 40 mg of metoclopramide per day. Parkinsonian-like symptoms may include bradykinesia, tremor, cogwheel rigidity, mask-like facies. Tardive dyskinesia most frequently is characterized by involuntary movements of the tongue, face, mouth, or jaw, and sometimes by involuntary movements of the trunk and/or extremities.

OVERDOSAGE

Symptoms of overdosage may include drowsiness, disorientation and extrapyramidal reactions. Anticholinergic or antiparkinson drugs or antihistamines with anticholinergic properties may be helpful in controlling the extrapyramidal reactions. Symptoms are self-limiting and usually disappear within 24 hours.

Hemodialysis removes relatively little metoclopramide, probably because of the small amount of the drug in blood relative to tissues. Similarly, continuous ambulatory peritoneal dialysis does not remove significant amounts of drug.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for METOCLOPRAMIDE Injection, USP.