FRESENIUS KABI

Metoclopramide
Injection, USP

10 mg per 2 mL Simplist® ready-to-administer prefilled syringe +RFID® is available from Fresenius Kabi.

- 36-month shelf life
- Manufacturer-embedded RFID tag
- Interoperable

*Medications that are administered intramuscularly require a needle be attached to the syringe.

Metoclopramide Injection, USP

IMPORTANT SAFETY INFORMATION:

WARNING: TARDIVE DYSKENISIA

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. See WARNINGS.

Metoclopramide is contraindicated and 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 is contraindicated and 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.

There have been rare reports of an uncommon but potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) associated with metoclopramide. Clinical manifestations of NMS include hyperthermia, muscle rigidity, altered consciousness, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac arrhythmias). Discontinue metoclopramide immediately and treat symptoms as appropriate.

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 and are even more frequent at the higher doses used in prophylaxis of vomiting due to cancer chemotherapy. These symptoms may include involuntary movements of limbs and facial grimacing, torticollis, oculogyric crisis, rhythmic protrusion of tongue, bulbar type of speech, trismus, or dystonic reactions resembling tetanus. Rarely, dystonic reactions may present as stridor and dyspnea, possibly due to laryngospasm. If these symptoms should occur, diphenhydramine hydrochloride injected intramuscularly may help symptoms subside. Benztropine mesylate injected intramuscularly may also be used to reverse these reactions.

Patients with preexisting Parkinson's disease should be given Metoclopramide cautiously, if at all, since such patients may experience exacerbation of Parkinsonian symptoms when taking Metoclopramide.

Metoclopramide should be given to patients with a prior history of depression only if the expected benefits outweigh the potential risks.

Because 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

The effects of metoclopramide on gastrointestinal motility are antagonized by anticholinergic drugs and narcotic analgesics. Additive sedative effects can occur when metoclopramide is given with alcohol, sedatives, hypnotics, narcotics, or tranquilizers.

Nursing Mothers: Metoclopramide is excreted in human milk. Caution should be exercised when metoclopramide is administered to a nursing mother.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established except as stated to facilitate small bowel intubation. The safety profile of metoclopramide in adults cannot be extrapolated to pediatric patients. Dystonias and other extrapyramidal reactions associated with metoclopramide are more common in the pediatric population than in adults.

Geriatric Use: The risk of developing Parkinsonian-like side effects increases with ascending dose. Geriatric patients should receive the lowest dose of Metoclopramide Injection that is effective. The elderly may be at greater risk for tardive dyskinesia.

Metoclopramide Injection is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function.

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: CNS effects (restlessness, drowsiness, fatigue and lassitude) may occur in patients receiving the recommended prescribed dosage, Extrapyramidal Reactions (most commonly acute dystonic reactions), Parkinsonian-like symptoms, Tardive dyskinesia, Motor restlessness (akathisia), Neuroleptic Malignant Syndrome, Endocrine Disturbances and Fluid Retention, Cardiovascular reactions (hypotension, hypertension, supraventricular tachycardia, bradycardia, fluid retention, acute congestive heart failure and possible atrioventricular (AVA) block, Gastrointestinal (nausea and bowel disturbances, primary diarrhea), Hepatotoxicity (rare), Renal (urinary frequency and incontinence) Hematologic (Methemoglobinemia in adults and especially with overdosage in neonates; Sulfhemoglobinemia in adults), Allergic reactions (rash, urticaria, or bronchospasm, especially in patients with a history of asthma), Visual disturbances, Porphyria, and Transient flushing of the face and upper body, without alterations in vital signs, following high doses intravenously.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 option 5 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS AND USAGE

Metoclopramide Injection, USP approved for intravenous or intramuscular injection is indicated for:

- the relief of symptoms associated with acute and recurrent diabetic gastric stasis
- prophylaxis of vomiting associated with emetogenic cancer chemotherapy
- prophylaxis of postoperative nausea and vomiting in those circumstances where nasogastric suction is undesirable
- to facilitate small bowel intubation in adults and pediatric patients in whom the tube does not pass the pylorus with conventional maneuvers
- 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

This Important Safety Information does not include all the information needed to use Metoclopramide Injection, USP safely and effectively. Please see accompanying full prescribing information, including BOXED WARNING, for Metoclopramide Injection, USP. Full prescribing information is also available at www.simplist-us.com.

Simplist®

Metoclopramide
Injection, USP

Strength	10 mg per 2 mL
Concentration	5 mg per mL
Fill volume	2 mL
Description	Single Dose Simplist® Prefilled Syringe
Unit of sale NDC	76045-213-20
Unit of sale bar code	N(01)30376045213202
Pack size	24 per Carton
Secondary packaging	Blister
Blister dimensions	5.748" x 1.063"
Carton dimensions	6.25" x 2.402" x 6.575"

Wholesale numbers

AmerisourceBergen	10287862
Cardinal	5912662
McKesson	2925337
Morris & Dickson	363333

To place an order, contact your Sales Representative or call Customer Service at 1.888.386.1300 | www.plusRFID.com

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