



נובמבר 2023

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

חברת רז רוקחות מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:

METOCLOPRAMIDE S.A.L.F 10 MG/2 ML

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא. התוספות סומנו בצבע כחול, ההחמרות סומנו בצהוב והמחיקות סומנו בצבע אדום עם קו מחיקה. העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות: www.health.gov.il, וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: רז רוקחות בע"מ, גשר בעץ 31, פארק תעשיות עמק חפר, ישראל.

מרכיב פעיל וחוזק: METOCLOPRAMIDE 10 MG / 2 ML

צורת מינון: SOLUTION FOR INJECTION

צורת מתן: I.M , I.V

התוויה מאושרת:

Adult population

METOCLOPRAMIDE S.A.L.F 10mg/2ml is indicated in adults for:

- Prevention of postoperative nausea and vomiting (PONV).
- Prevention of delayed nausea and vomiting caused by chemotherapy (delayed CINV).
- Prevention of nausea and vomiting caused by radiation therapy.
- Symptomatic treatment of nausea and vomiting, including nausea and vomiting caused by migraine attack. In migraine attacks, metoclopramide can be used concomitantly with oral analgesics to improve their absorption.
- Diabetic gastroparesis.
- To facilitate diagnostic procedures (i.e., to facilitate small bowel intubation and as an aid in radiological examinations).

Pediatric population

METOCLOPRAMIDE S.A.L.F 10mg/2ml is indicated in children aged 1 to 18 years for:

- Second line-therapy: Treatment of established postoperative nausea and vomiting (PONV).
- Second-line therapy: Prevention of delayed nausea and vomiting caused by chemotherapy (delayed CINV).
- To facilitate diagnostic procedures (i.e., to facilitate small bowel intubation and as an aid in radiological examinations).

להלן העדכונים המהותיים שבוצעו בעלון לרופא:

[...]

3. PHARMACEUTICAL FORM

Solution for I.V or I.M injection.

Clear colorless solution.

[...]

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Gastrointestinal hemorrhage, mechanical obstruction or gastro-intestinal perforation for which the stimulation of gastrointestinal motility constitutes a risk.
- Confirmed or suspected pheochromocytoma, due to the risk of severe hypertension episodes.
- History of neuroleptic or metoclopramide-induced tardive dyskinesia.
- Epilepsy (increased frequency and intensity).



- Parkinson's disease.
- Combination with levodopa or dopaminergic agonists (see section 4.5)
- Known history of methemoglobinemia with metoclopramide, or of NADH cytochrome- b5 reductase deficiency.
- Use in children less than 1 year of age due to an increased risk of extrapyramidal disorders (see section 4.4).
- Metoclopramide S.A.L.F 10mg/2ml should not be used during the first three to four days following operations such as pyloroplasty or gut anastomosis as vigorous muscular contractions may adversely affect healing.
- **Metoclopramide should not be used during breast-feeding** (see Section 4.6).

[...]

4.4 Special warnings and precautions for use

[...]

Cardiac disorders

There have been reports of serious cardiovascular undesirable effects and abnormalities of cardiac conduction including cases of circulatory collapse, severe bradycardia, cardiac arrest and QT prolongation following administration of metoclopramide by injection, particularly via the intravenous route (see section 4.8).

Special care should be taken when administering metoclopramide, particularly via the intravenous route to the elderly population, to patients with cardiac conduction disturbances (including QT prolongation), patients with uncorrected electrolyte imbalance, bradycardia and those taking other drugs known to prolong QT interval

Special care should be taken when administering metoclopramide S.A.L.F 10mg/2ml intravenously to patients with 'sick sinus syndrome' **or other conduction disturbances.**

[...]

4.6 Fertility, pregnancy and lactation

[...]

Fertility

No data available.

[...]

4.8

[...]

System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders		
	Not known	Methemoglobinemia, which could be related to NADH cytochrome-b5 reductase deficiency, particularly in neonates in whom the use is contraindicated (see section 4.4). Sulfhemoglobinemia, mainly with concomitant administration of high doses of sulfur-releasing medicinal products
Cardiac disorders		
	Uncommon	Bradycardia, particularly with intravenous formulation.



	Not known	Cardiac arrest, occurring shortly after injectable use, and which can be subsequent to bradycardia (see section 4.4); Atrioventricular block, Sinus arrest particularly with intravenous formulation ; Electrocardiogram QT prolonged; Torsade de pointes
Endocrine disorders*		
	Uncommon	Amenorrhea, Hyperprolactinemia
	Rare	Galactorrhea
	Not known	Gynecomastia
Gastrointestinal disorders		
	Common	Diarrhea
General disorders and administration site conditions		
	Common	Asthenia
	Not Known	Injection site inflammation and local phlebitis
Immune system disorders		
	Uncommon	Hypersensitivity
	Not known	Anaphylactic reaction (including anaphylactic shock) particularly with intravenous formulation .
Nervous system disorders		
	Very common	Somnolence
	Common	Extrapyramidal disorders (particularly in children and young adults and/or when the recommended dose is exceeded, even following administration of a single dose of the drug) (see section 4.4), Parkinsonism, Akathisia
	Uncommon	Dystonia (including visual disturbances and oculogyric crisis), Dyskinesia, Depressed level of consciousness
	Rare	Convulsion especially in epileptic patients
	Not known	Tardive dyskinesia which may be persistent, during or after prolonged treatment, particularly in elderly patients (see section 4.4), Neuroleptic malignant syndrome (see section 4.4)
Psychiatric disorders		
	Common	Depression
	Uncommon	Hallucination



	Rare	Confusional state
Vascular disorders		
	Common	Hypotension, particularly with intravenous formulation .
	Not known	Shock, syncope after injectable use. Acute hypertension in patients with pheochromocytoma (see section 4.3) Transient increase in blood pressure
Skin disorders		
	Not known	Skin reactions such as rash, pruritus, angioedema and urticaria

בברכה,

אריאל מימון

מנהלת מחלקת רישום

רז רוקחות בע"מ