



2024 ספטמבר

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**

METOCLOPRAMIDE HYDROCHLORIDE 5 MG/ML: **פעיל: חומר**

**צורת מינון:** SOLUTION FOR INJECTION

**התוויות מאושרות:**

- 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 (ie, to facilitate small bowel intubation and as an aid in radiological examinations) Pediatric population.
- METOCLOPRAMIDE S.A.L.F 10 MG/2 ML 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 (ie, to facilitate small bowel intubation and as an aid in radiological examinations).

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא.

התוספות סומנו בצבע כחול, החמרות סומנו בצהוב, מחיקות בקו חוצה אדום.  
העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות : [www.health.gov.il](http://www.health.gov.il), וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: רז רוקחות בע"מ, גשר בע"מ 31, פארק עשיות עמק חפר, ישראל.

בברכה,  
מאיה אריאלי  
רוקחת ממונה

העדכונים בעלון לרופא:



[...]

#### 4.4 Interactions with other medicinal products and other forms of interaction

[...]

##### Cardiac disorders

[...]

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. (e.g., class IA and III antiarrhythmic drugs, tricyclic antidepressants, macrolides, antipsychotics (see section 4.8)).

[...]

#### 4.5 Interactions with other medicinal products and other forms of interaction

##### Rifampicin

In a published study conducted in 12 healthy volunteers, the administration of 600 mg of rifampicin for 6 days led to reduced plasma metoclopramide exposure (AUC area under the curve) and maximum concentration (C<sub>max</sub>) by 68% and 35%, respectively. Although the clinical significance is uncertain when metoclopramide is combined with rifampicin, or with other strong inducers (e.g. carbamazepine, phenobarbital, phenytoin), patients should be monitored for a possible lack of anti-emetic activity.

[...]

## 5.2 Pharmacokinetic properties

[...]

### Absorption

Metoclopramide is rapidly absorbed from the gastrointestinal tract and undergoes variable first-pass metabolism in the liver.

After intramuscular administration, the relative bioavailability compared to intravenous



application is 60 to 100 %. Peak plasma levels are reached within 0.5 to 2 hours.

**Distribution:**

The distribution volume is 2-3 l/kg; 13-22% is bound to plasma proteins.

[...]

Elimination

The predominant route of elimination of metoclopramide and its metabolites is via the kidney, both in unchanged form and in sulfate or glucuronide conjugate form. The main metabolite is N-4 sulfur conjugate. It crosses the placenta and is excreted in breast milk. The elimination half-life is about 5 to 6 hours, regardless of the route of administration.