

רופא/ה, חוקח/ת נכבד/ה,

עדכון עלונים - Pramin injection

מעבדות רפא מבקשת להודיעך על עדכון בעלון לצרכן (במתכונת עלון לרופא) של התכשיר שבנדון.

מרכיב פעיל : Metoclopramide hydrochloride
 חוזק: 10 mg/2 ml

התוויה :

Metoclopramide is an antiemetic and stimulates GI motility.

Adult population

Pramin® Injection 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

Pramin® Injection 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).

פרטי העדכון העיקריים בעלון לצרכן (במתכונת עלון לרופא) הינם:

(טקסט שהושמט מסומן באדום עם קו חוצה, טקסט שנוסף מסומן בכחול, טקסט המהווה החמרה מודגש בצהוב).

4.4 Special warnings and precautions for use

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

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4.5 Interactions with other medicinal products and other forms of interaction

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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_{max}) 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.

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5.2 Pharmacokinetic properties

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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.

Biotransformation:

Metoclopramide is metabolised 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, **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.**

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למידע המלא יש לעיין בעלונים המפורסמים בצמוד להודעה זו.
 העלונים פורסמו **במאגר התרופות של משרד הבריאות**. ניתן לקבל העתק מודפס שלהם באמצעות פנייה לחברת מעבדות רפא בע"מ בטל': 02-5893939 או בכתובת דוא"ל RA@rafa.co.il.

בכבוד רב,
 מעבדות רפא