

דצמבר 2025

PARACETAMOL FRESENIUS 10 mg/ml

פראצטמול פרזניאוס 10 מ"ג/מ"ל

מרכיב פועל: Paracetamol 10MG/ML

צורת מינן: solution for infusion

רופא/ה, רוקחת/ת נכבד/ה,
חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון. העלון עודכן בתאריך נובמבר 2025.

ההתוויה הרשומה לתכשיר בישראל:

Paracetamol Fresenius 10 mg/ml is indicated for:

- short-term treatment of moderate pain, especially following surgery.
- short-term treatment of fever.

when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

מרקם לעדכנים המסומנים:

מידע שהוסר - מסומן בקוו אדום חוצה XXX

תוספת - כתוב כחול

תוספת החרמלה - כתוב כחול - מסומן בצהוב מרתק

עדכנים מוחותיים נעשו בסעיפים הבאים לעלון לרופא:

3. PHARMACEUTICAL FORM

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The solution is clear colorless to almost colorless solution.

The solution pH is between 5.0 and 7.0.

4.2 Posology and method of administration

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Only to be used if solution is clear, clear colourless to almost colorless solution and the container and its closure are undamaged.

4.4 Special warnings and precautions for use

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Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors. Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism),

~~as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.~~

4.8 Undesirable effects

As with all paracetamol products, adverse drug reactions are rare ($\geq 1/10,000$ to $<1/1,000$) or very rare ($<1/10,000$). They are described below:

System Organ Class	Rare ($\geq 1/10,000$ to $<1/1,000$)	Very rare ($<1/10,000$)	Not known (cannot be estimated from the available data)
(...)			
<i>Metabolism and nutrition disorders</i>			High anion gap metabolic acidosis
(...)			

Description of selected adverse reactions

High anion gap metabolic acidosis

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4).

Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

6.6 Special precautions for disposal and other handling

Paracetamol Fresenius 10 mg/ml can be diluted in 9 mg/ml (0.9%) sodium chloride solution for infusion or 50 mg/ml (5%) glucose solution for infusion ~~or a combination of both solutions~~ up to one tenth. For shelf life after dilution see section 6.3.

קיימים בעלון עדכונים נוספים. מידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא העלון/לצורך נשלחו לפרסום במאג'ר התרופות שבא'ר' משורד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום ניאופרם (ישראל) 1996 בע"מ, בנין ניאופרם, רח' השילוח 6 ת.ד. 7063 פתח-תקווה 4917001, טלפון: 03-9373737, פקס: 03-9373770

בברכה,

עוד ווילך

רוחח ממונה של בעל הרישום