ספטמבר 2025

רופא/ה, רוקח/ת נכבד/ה,

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

PARACETAMOL S.A.L.F 10 MG/ML
פרצטמול ס.א.ל.פ 10 מ"ג/מ"ל
SOLUTION FOR INFUSION (I.V.)

המרכיב הפעיל:

PARACETAMOL 10 MG/1 ML

התוויה מאושרת:

Paracetamol is indicated for the short-term treatment of moderate pain, especially following surgery and for the short-term treatment of fever, when intravenous administration is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא.
שינויים בעלון המהווים החמרה מודגשים ברקע צהוב, תוספות מסומנות בצבע אדום והשמטות מסומנות בקו ~~אופקי~~. למידע נוסף יש לעיין בעלון לרופא המאושר.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות (www.health.gov.il), וניתן גם לקבלו מודפס ע"י פניה לבעל הרישום:
רז רוקחות בע"מ, רחוב גשר העץ 31, פארק תעשיות, עמק חפר, ובטלפון 04-9079710.

בברכה,

ויויאן ארדיטי
רוקחת ממונה
רז רוקחות בע"מ

העדכונים המהותיים שבוצעו בעלון לצרכן:

[...]

4.4 Special warnings and precautions for use

[...]

Paracetamol should be used with caution in cases of:

- hepatocellular insufficiency
- severe renal insufficiency (creatinine clearance ≤ 30 ml/min) (see sections 4.2 and 5.2)
- chronic alcoholism
- chronic malnutrition (low reserves of hepatic glutathione)
- dehydration
- patients suffering from a genetically caused G-6-PD deficiency (favism), the occurrence of a haemolytic anaemia is possible due to the reduced allocation of glutathione following the administration of paracetamol.

~~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.~~Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been re-ported 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 flu-cloxacillin. 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.

~~Excipients~~

This ~~medicinal product~~medicine contains less than 1 mmol sodium (23 mg) per 100 ml of solution, i.e. ~~it is~~ essentially ‘~~"~~sodium-free’~~"~~.

This ~~medicinal product~~medicine contains 3.3 ~~mg/ml~~g of glucose monohydrate per 100 ml of solution ~~for infusion~~. This should be ~~To be~~ taken into account in patients with diabetes mellitus.

4.5 Interaction with other medicinal products and other forms of interaction

- **Probenecid** causes an almost two-fold reduction in clearance of paracetamol by inhibiting its conjugation with glucuronic acid. A reduction in the paracetamol dose should be considered if it is to be used concomitantly with probenecid.
- **Salicylamide** may prolong the elimination half-life of paracetamol.
- Caution should be taken with the concomitant intake of **enzyme-inducing substances** (see section 4.9).
- Concomitant use of paracetamol (4000 mg per day for at least 4 days) with **oral anticoagulants** may lead to slight variations of INR values. In this case, increased monitoring of INR values should be

conducted during the period of concomitant use as well as for 1 week after paracetamol treatment has been discontinued.

- Caution should be taken when paracetamol is used concomitantly with **flucloxacillin** as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4).

[...]

4.8 Undesirable effects

As with all paracetamol products, adverse drug reactions are rare (≥1/10000 to <1/1000) or very rare (<1/10000). They are described below:

System Organ Class	**Rare** (≥1/10000 to <1/1000)	**Very rare** (<1/10000)	**Not known** (cannot be estimated from the available data)
General- disorders and administration site conditions	Malaise	-	-
Vascular disorders	Hypotension	-	Flushing (2)
Hepatobiliary disorders	Increased levels of hepatic transaminases	-	-
Blood and the lymphatic system disorders	-	Thrombocytopenia, Leucopenia, Neutropenia	-
Immune system disorders	-	Hypersensitivity reaction (1, 3)	-
Metabolism and nutrition disorders	-	-	High anion gap metabolic acidosis
Cardiac disorders	-	-	Tachycardia (2)
Skin and subcutaneous tissue disorders	-	serious skin reactions (3)	Pruritus (2), Erythema (2)

(1) Very rare cases of hypersensitivity reactions ranging from simple skin rash or urticaria to anaphylactic shock have been reported and require discontinuation of treatment.
(2) Isolated cases
(3) Very rare cases of serious skin reactions have been reported.

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.

Frequent adverse reactions at injection site have been reported during clinical trials (pain and burning sensation).

[...]