אפריל 2020

רופא/ה נכבד/ה
רוקח/ת נכבד/ת

**חברת תרו מבקשת להודיעכם כי העלון לרופא של התכשיר Paracetamol Taro IV 10mg/ml, solution for infusion, עודכן.**

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא. תוספות סומנו בצבע אדום.

העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
www.health.gov.il וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום:
תרו אינטרנשיונל בע"מ, רחוב הקיטור 14, ת.ד 10347 מפרץ חיפה 2624761 .

בברכה,
מרינה גולדמן
רוקחת ממונה

# Paracetamol Taro IV 10mg/ml, solution for infusion

**מרכיב פעיל:**

Paracetamol 10mg/ml

**ההתוויה המאושרת לתכשיר:**

For the short-term treatment of moderate pain, especially following surgery and for the 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.

**עדכונים בעלון לרופא:**

## *4.4 Special warnings and precautions during administration*

***Warnings***

- Doses higher than the recommended ones entails risk for hepatic injury, including the risk of severe hepatotoxicity and death. Do not exceed the maximum recommended daily dose of paracetamol. Clinical symptoms and signs of liver damage are usually first seen after two days of drug administration, with a peak seen usually after 4 - 6 days.

***Precautions during administration***

Reddening of the skin, rash, blisters, and detachment of the upper surface of the skin can occur with the use of drug products that contain paracetamol. These reactions can occur

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with first-time use of paracetamol or at any time while it is being taken.

Anyone who develops a skin rash or reaction while using paracetamol should stop the drug and seek medical attention right away. Anyone who has experienced a serious skin reaction with paracetamol should not take the drug again and should contact their health care professional to discuss alternative pain relievers/fever reducers.

Health care professionals should be aware of this rare risk and consider paracetamol along with other drugs already known to have such an association, when assessing patients with potentially drug induced skin reactions.

***Precautions for use***

Paracetamol should be used with caution in cases of:

- Hepatocellular insufficiency, or active hepatic disease.
- Severe renal insufficiency (creatinine clearance ≤ 30 ml/min) (see sections 4.2 *Posology and method of administration* and 5.2 *Pharmacokinetic properties*).
- Chronic alcoholism.
- Chronic malnutrition (low reserves of hepatic gluthatione).
- Severe hypovolemia (e.g., due to dehydration or blood loss).

### *Effects of other substances on paracetamol*

Substances that induce or regulate hepatic cytochrome enzyme CYP2E1 may alter the metabolism of paracetamol and increase its hepatotoxic potential. The clinical consequences of these effects have not been established. Effects of ethanol are complex, because excessive alcohol usage can induce hepatic cytochromes, but ethanol also acts as a competitive inhibitor of the metabolism of paracetamol.

## *4.8 Adverse Reactions*

Very rare cases of hypersensitivity reactions ranging from dyspnea, hypotension and skin rash or urticaria to anaphylactic shock have been reported. Clinical signs include swelling of the face, mouth and throat, respiratory distress, urticaria, rash and pruritis. Discontinue Paracetamol Taro I.V. 10 mg/ml immediately if symptoms associated with allergy or hypersensitivity occur. Isolated reports of thrombocytopenia have been observed. Cases of erythema, flushing, pruritus and tachycardia have been reported.

## *4.9 Overdose*

In acute paracetamol overdosage, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may also occur. Plasma paracetamol levels > 300 mcg/ml at 4 hours after oral ingestion were associated with hepatic damage in 90% of patients; minimal hepatic damage is anticipated if plasma levels at 4 hours are < 150 mcg/ml or < 37.5 mcg/ml at 12 hours after ingestion.

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There is a risk of liver injury (including fulminant hepatitis, hepatic failure, cholestatic hepatitis, cytolytic hepatitis), particularly in elderly patients and young children, patients with liver disease, in cases of chronic alcoholism, patients with chronic malnutrition and patients receiving enzyme inducers. Overdosing may be fatal in these cases.Symptoms generally appear within the first 24 hours and comprise: nausea, vomiting, anorexia, pallor, abdominal pain, diaphoresis and general malaise.

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