

מאי, 2025

COMBODEX IV, SOLUTION FOR INFUSION

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר קומבודקס תוך ורידי. בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלון. העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

הרכב התכשיר:

Each 100 ml vial contains Ibuprofen (as Sodium Dihydrate) 300 mg and Paracetamol 1000 mg.

התוויות מאושרות:

Combodex IV is indicated for the relief of mild to moderate pain and the reduction of fever, where an intravenous route of administration is considered clinically necessary.

העלון לרופא עודכן במאי 2025. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

4.4 Special warnings and precautions for use

[...]

Do not give anything else containing paracetamol while giving this medicine.

In order to avoid the risk of overdose,

- check that other medicinal products do not contain paracetamol **or ibuprofen**,
- observe the maximum recommended doses (see section 4.2).

[...]

Renal impairment

[...]

Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose.

4.8 Undesirable effects

[...]

Metabolic and nutrition disorders	[...] Not Known: Hypokalaemia ¹ , High anion gap metabolic acidosis ³ .
Renal and urinary disorders	[...] Not Known: Renal tubular acidosis ¹

Description of selected adverse events

1. Renal tubular acidosis and hypokalaemia have been reported in the post-marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses.
2. Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).
3. 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.

[...]

4.9 Overdose

Ibuprofen

Symptoms include nausea, abdominal pain and vomiting, dizziness, convulsion and rarely, loss of consciousness. Clinical features of overdose with ibuprofen which may result are depression of the central nervous system and the respiratory system. In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Prolonged use at higher than recommended doses may result in severe hypokalaemia and renal tubular acidosis. Symptoms may include reduced level of consciousness and generalised weakness (see sections 4.4 and 4.8).

[...]