

Paracetamol 1000 mg I.V. Solution for Infusion Dosing Card

[This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA]

Caution in Use: Risk of Medication Errors

1 vial contains 1000 mg of paracetamol in 100 ml

Use of the product Paraconica 1000 mg I.V. solution for infusion is restricted to patients weighing more than 33 kg

Take care when prescribing and administering paracetamol to avoid dosing errors due to confusion between milligram (mg) and milliliter (ml), which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. When writing prescriptions, include both the total dose in mg and the total dose in volume.

Paracetamol 10 mg/ml Dosing Based on Patient's Weight for 100 ml vial

Patient weight	Dose per administration	Volume per administration	Maximum daily dose*
>50 kg	1 g	100 mL	4 g
>33 kg to ≤ 50 kg	15 mg/kg	1.5 ml/kg	60 mg/kg
>33 kg with risk factors for hepatotoxicity**	Paraconica dose must be reduced or the time between doses must be increased		2 g

*To avoid the risk of an overdose, it must be ensured that other administered medicinal products (prescription-only and OTC) contain no paracetamol.

**Patients with chronic or compensated, active liver disease, especially with mild-to-moderate hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione) or dehydration, as well as in adult cachectic patients, the dose must be reduced or the dosing interval prolonged and the daily dose must not exceed 2 g paracetamol.

The minimum interval between each administration must be at least 4 hours. No more than 4 doses to be given in 24 hours.

In patients with severe renal insufficiency (creatinine clearance 10–30 mL/min), the time between Paraconica doses should be extended to 6 hours.

I.V. - intravenous; *OTC* - over the counter; *SmPC* - summary for product characteristics.

Paracetamol 10 mg/ml Dosing Guide for 100 ml vial

Patient's weight (kg)	Dose per administration (mg)	Volume per administration (ml)
34	510,0	51,0
36	540,0	54,0
38	570,0	57,0
40	600,0	60,0
42	630,0	63,0
44	660,0	66,0
46	690,0	69,0
48	720,0	72,0
50	750,0	75,0
>50	1000,0	100,0

Paraconica is a ready-to-use solution. It is administered as a 15-minute I.V. infusion. Efficacy and safety of slower or faster administration have not been investigated.

Before use, please read locally approved SPC for Paraconica 1000 mg I.V.

To **report adverse events** or any safety information:

- The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority:

Call Center: 19999
E-mail: npc.drug@sFDA.gov.sa
Fax: +966-11-205-7662
Website: <https://ade.sFDA.gov.sa/>

- Acino contact information:

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