Paracetamol

10 mg/ml solution for infusion

Risk of Medication Errors Leading to Accidental Overdose

Patients at increased risk of overdose include:

- Neonates
- Underweight adults (≤ 50 kg)
- factors for hepatotoxicity (e.g. hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione) and dehydration).

Cases of accidental overdose have been reported during treatment with intravenous paracetamol 10mg/ml solution for infusion. In some cases this occurred due to the confusion between the prescription being issued in mg and then being administered in mL, resulting in a 10-fold overdose (particularly in neonates). Errors related to accidental overdose of adults weighing ≤50kg (who require weight-based dosing 60mg/kg not exceeding 3g) resulting in serious hepatotoxicity have also been reported.

1ml solution = 10mg paracetamol

DOSAGE IS DEPENDENT ON THE PATIENT WEIGHT.[1] THE VOLUMES ADMINISTERED CAN BE VERY LOW.

Minimum interval between doses is 4 hours. Note: may need longer interval time in abnormal renal functions see SmPC

Dosing based on patient weight

	Paracetamol 10 mg/ml, 50 ml		Paracetamol 10mg/ml, 100 ml		
	Patient weight ≤ 10 kg	Patients > 10 Kg to ≤ 33 kg	Patients > 33 kg to ≤ 50 kg	Patients > 50 kg with additional risk factors for hepatotoxicity*	Patients > 50 kg and no additional risk factors for hepatotoxicity*
Dose per administration	7.5 mg/kg	15 mg/kg	15 mg/kg	1000 mg	1000 mg
Volume per administration	0.75 mL/kg	1.5 mL/Kg	1.5 mL/Kg	100 ml	100 ml
Maximum volume per administration based on upper weight limits of group	7.5 mL	49.5 mL	75 ml	100 ml	100 ml
Maximum daily dose	30 mg/kg	2 g	3 g	3 g	4 g

Dosing guide Infants and Children up to 10kg:

Patient weight*	Dose per administration	Volume per administration
1kg	7.50 mg	0.75 ml
2kg	15.00 mg	1.50 ml
3kg	22.50 mg	2.25 ml
4kg	30.00 mg	3.00 ml
5kg	37.50 mg	3.75 ml
6kg	45.00 mg	4.50 ml
7kg	52.50 mg	5.25 ml
8kg	60.00 mg	6.00 ml
9kg	67.50 mg	6.75 ml
10kg	75.00 mg	7.50 ml

- In children with low weights, Paracetamol can be diluted in a 0.9% sodium chloride solution or a 5% glucose solution up to one tenth.
- In order to avoid the risk of overdose, check that other medicines administered do not contain either paracetamol or propacetamol hydrochloride.
- In case of overdose, consider the following: hospitalisation, symptomatic treatment, administration of N-acetylcysteine (antidote), blood samples (liver function tests, plasma paracetamol assay). Effects of hemodialysis are limited. Severe cases may demand liver transplantation. For detailed procedure, refer to the SmPC and/or consult an expert toxicologist.
- *Risk factors for hepatotoxicity include [chronic or compensated active hepatic disease, hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione), dehydration, Meulengracht Gilbert Syndrome]

1. Summary of Product Characteristics Paracetamol 10 mg/ml solution for infusion. Fresenius Kabi Deutschland GmbH.

Adverse events should be reported. Reporting forms and information can be found at HPRA Pharmacovigilance Website: www.hpra.ie.

FRESENIUS KABI

Job Code: IE--2500013
Date of Preparation: August 2025