

# Paracetamol Kabi

## 10 mg/ml solution for infusion

### Risk of overdose in newborn infants, infants and underweight adults with intravenous paracetamol by error of administration

Indication: 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.<sup>(1)</sup>

**DOSAGE DEPENDING ON THE PATIENT WEIGHT. THE VOLUMES ADMINISTERED CAN BE VERY LOW.**

#### Dosing based on patient weight<sup>(1)</sup>

	Patient weight ≤ 10 kg	Patient weight > 10 kg to ≤ 50 kg
To Operating theatre	7.5 mg/kg <b>i.e. 0.75 ml/kg</b>	15 mg/kg <b>i.e. 1.5 ml/kg</b>
↓ minimum interval 4 hours	7.5 mg/kg	15 mg/kg
	No more than 4 administrations of 7.5 mg/kg paracetamol without exceeding 30 mg/kg/24 hours	1 IV infusion of 15 mg/kg/4 to 6 hours without exceeding 60 mg/kg/24 hours

(Posology expressed in mg paracetamol per kg body weight)

**Paracetamol Kabi**  
10 mg/ml, 50 ml  
**1 ml = 10 mg**

Restricted to term newborn infants, infants, toddlers and children weighing up to 33 kg<sup>(1)</sup>



- Term newborn infants, infants, toddlers and children weighing up to 10 kg:  
7.5 mg/kg, i.e. 0.75 ml/kg per administration, up to 4 times a day.
- Children weighing more than 10 kg and up to 33 kg:  
15 mg/kg, i.e. 1.5 ml/kg per administration, up to 4 times a day.

**Dosage examples**

Child's weight	Volume to be taken
2 kg	1.5 ml
2.5 kg	1.8 ml
3 kg	2.25 ml

**Paracetamol Kabi**  
10 mg/ml, 100 ml  
**1 ml = 10 mg**

Restricted to adults, adolescents and children weighing more than 33 kg<sup>(1)</sup>



- Adults and adolescents weighing more than 50 kg: see product information
- Children weighing more than 33 kg, adolescents and adults weighing up to 50 kg:  
15 mg/kg i.e. 1.5 ml/kg per administration, up to 4 times a day.

- In children with low weights, Paracetamol Kabi 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 (for detailed procedure refer to SmPC and expert toxicologist): 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.

<sup>1)</sup> Summary of Product Characteristics Paracetamol Kabi.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)



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