Paracetamol Kabi 10 mg/ml

1 ml contains 10 mg

≤ 50 kg

Dosing of Paracetamol for patients ≤ 50 kg

Patients weight	Dose (dependent on weight)*	Maximum dose
≤ 10 kg	7.5 mg/kg **i.e. 0.75 ml/kg**	30 mg/kg **i.e. 3 ml/kg**
> 10 kg - ≤ 50 kg	15 mg/kg **i.e. 1.5 ml/kg**	60 mg/kg **i.e. 6 ml/kg**

> 50 kg

Dosing of Paracetamol for patients > 50 kg

Patients weight	Dose*	Maximum dose
> 50 kg	1,000 mg **i.e. 100 ml**	4,000 mg **i.e. 400 ml**

* **Dosing interval:** Minimum interval for repeated administration: 4 hours; no more than 4 administrations per 24 hours

Paracetamol is presented in two vials:

- The 100 ml vial is restricted to patients weighing more than 33 kg.
- The 50 ml vial is restricted to patients weighing up to 33 kg.

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Abbreviated Prescribing Information

Paracetamol Kabi 10 mg/ml solution for infusion
Active Ingredient (s): 1 ml contains 10 mg paracetamol. Each 50 ml vial contains 500 mg paracetamol. Each 100 ml vial contains 1000 mg paracetamol. **Indication (s):** Paracetamol Kabi 10 mg/ml solution for infusion is indicated for the short-term treatment of moderate pain, especially following surgery, 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. **Dosage and administration:** Intravenous use. The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg. The 50 ml vial is restricted to term newborn infants, infants, toddlers and children weighing up to 33 kg. **Contraindications:** Hypersensitivity to the active substance, propacetamol hydrochloride (prodrug of paracetamol) or to any of the excipients. Severe hepatocellular insufficiency (Child-Pugh >9). **Special warnings and precautions for use:** RISK OF MEDICATION ERRORS. Take care to avoid dosing errors due to confusion between milligram (mg) and millilitre (ml), which could result in accidental overdose and death (see section 4.2). It is recommended to use a suitable analgesic oral treatment as soon as this route of administration is possible. In order to avoid the risk of overdose, check that no other medicinal products administered do contain paracetamol or propacetamol hydrochloride. Doses higher than those recommended entail the risk of very serious liver damage. Clinical signs and symptoms of hepatic damage (including fulminant hepatitis, hepatic failure, cholestatic hepatitis, cytolytic hepatitis) are not usually seen until two days, and up to a maximum of 4-6 days, after administration. Treatment with antidote should be given as soon as possible (see section 4.9). Paracetamol should be used with particular caution under the following circumstances: Abnormal Liver Function and Hepatocellular insufficiency (Child-Pugh ≤ 9), Hepatobiliary disorders, Meulengracht Gilbert Syndrome (familial non-haemolytic jaundice), Severe renal insufficiency (creatinine clearance ≤30 ml/min), see sections 4.2 and 5.2, Chronic alcohol abuse, Chronic malnutrition (low reserves of hepatic glutathione), Total parenteral nutrition (TPN) use, Use of enzyme inducers, Use of hepatotoxic agents, In patients suffering from a genetically caused G-6-PD deficiency (favism) the occurrence of a haemolytic anaemia is possible due to the reduced allocation of glutathione following the administration of paracetamol, Dehydration. **Undesirable effects:** As with all paracetamol containing medicinal products, undesirable effects are rare or very rare. Rare: Hypotension, malaise, transaminases increased. Very rare: Thrombocytopenia, leukopenia, neutropenia, agranulacytosis, hypersensitivity (ranging from simple skin rash or urticaria to anaphylactic shock which requires immediate discontinuation of treatement), bronchospasm. Not known: Tachycardia, erythema, flushing, and pruritus. **Legal Category:** POM. **Marketing Authorisation Holder:** Fresenius Kabi Italia S.r.l. Via Camagre 41, 37063 Isola della Scala, Verona. **Further Information:** See full Summary of Product Characteristics for further details. **Adverse events should be reported.** 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. **Date of revision:** June 2019

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(07/12 DBM)