Perfalgan®

paracetamol 10 mg/mL

SOLUTION FOR INFUSION

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.[1]

CAUTION IS REQUIRED WHEN ADMINISTERING PERFALGAN® 10 mg/mL TO AVOID CONFUSION BETWEEN MILLIGRAM (mg) and MILLILITRE (mL), WHICH COULD RESULT IN ACCIDENTAL OVERDOSE OR DEATH.

Take care when prescribing and administering Perfalgan® to avoid dosing errors due to confusion between milligram (mg) and millilitre (mL). When writing prescriptions, include both the total dose in mg and the total volume in mL. Take care to ensure the dose is administered accurately following the specific recommendations to the paediatric population (see recommendations below).

Administration protocol in term neonates, infants and children weighing less than 10 kg [1]

(Dosage expressed in mg/kg paracetamol)

1 mL = 10 mg paracetamol

Patient weight	Single dose	Maximum daily dose**
⩽ 10 kg*	7.5 mg/kg i.e. 0.75 mL/kg	• Up to four times a day • The minimum interval between each administration must be 4 hours • The maximum daily dose must not exceed 30 mg/kg

* Pre-term newborn infants: No safety and efficacy data are available for pre-term newborn infants.

** Maximum daily dose: The maximum daily dose as presented in the table above is for patients that are not receiving other paracetamol-containing products and should be adjusted accordingly taking such products into account.

The volume of Perfalgan® 10 mg/mL administered should never exceed 7.5 mL per dose in patients weighing ⩽ 10 kg.

Child's weight ⩽ 10 kg	Volume of vial to be used	Corresponding amount of paracetamol in mg
1 kg	0.75 mL	7.5 mg
1.5 kg	1.1 mL	11 mg
2 kg	1.5 mL	15 mg
2.5 kg	1.8 mL	18 mg
3 kg	2.2 mL	22 mg
3.5 kg	2.6 mL	26 mg
4 kg	3.0 mL	30 mg
4.5 kg	3.3 mL	33 mg
5 kg	3.7 mL	37 mg
5.5 kg	4.1 mL	41 mg
6 kg	4.5 mL	45 mg
6.5 kg	4.8 mL	48 mg
7 kg	5.2 mL	52 mg
7.5 kg	5.6 mL	56 mg
8 kg	6.0 mL	60 mg
8.5 kg	6.3 mL	63 mg
9 kg	6.7 mL	67 mg
9.5 kg	7.1 mL	71 mg
10 kg	7.5 mL	75 mg

For patients weighing ⩽ 10 kg, the following recommendations apply:

- **Do not hang the vial as an infusion.**
- **Use a 5 mL or 10 mL syringe to measure the dose as appropriate for the weight of the child and the desired volume.**
- **The volume to be administered should be withdrawn from the vial and could be administered undiluted or diluted (from one to nine volumes diluent) in a 0.9% sodium chloride solution or 5% glucose solution and administered in 15 minutes.**
- **Use the diluted solution within the hour following its preparation (infusion time included).**

This poster is part of the Risk Management Plan of Perfalgan® to minimise the risk of overdose.

Reporting of 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 Freepost, HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com

1) Summary of Product Characteristics of Perfalgan® 10 mg/mL, solution for infusion.

Bristol-Myers Squibb

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