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)
- Patients with additional risk factors for hepatotoxicity (e.g. hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione) and dehydration).

In order to avoid overdose, intravenous paracetamol should not be given concomitantly with oral paracetamol, including combination products.

Risk of Medication Errors
Cases of accidental overdose have been reported during treatment with intravenous Paracetamol 10 mg/ml solution for infusion. In most cases, this occurred in infants and neonates due to confusion between the prescription of Paracetamol being issued in mg and then administered in ml; in most of these cases, a 10-fold overdose was reported. 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. Take care when dispensing Paracetamol 10 mg/ml solution for Infusion to avoid dosing errors due to confusion between milligram (mg) and millilitre (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. Take care to ensure the dose is measured and administered accurately.

1mL solution = 10mg paracetamol.

Dosing information related to patients weighing less than 33 kg have been shaded in grey as, although not strictly applicable to the Accord products, it is important for you to have access to the full dosage range.

Dosing based on <u>patient weight</u> is presented in the table below:

Patient weight	Dose per administration	Volume per administration	Maximum volume of Paracetamol (10 mg/ml) per administration based on upper weight limits of group (ml)***	Maximum Daily Dose **
^Newborn infants, infants and children ≤10 kg *	7.5 mg/kg	0.75 ml/kg	7.5 ml	30 mg/kg
^Children >10 kg to ≤33kg	15 mg/kg	1.5 ml/kg	49.5 ml	60 mg/kg not exceeding 2 g
Children, adolescents and adults >33 kg to ≤50kg	15 mg/kg	1.5 ml/kg	75 ml	60 mg/kg not exceeding 3 g
Adolescents and adults >50kg with additional risk factors for hepatotoxicity^^	1 g	100 ml	100 ml	3 g
Adolescents and adults >50 kg and no additional risk factors for hepatotoxicity	1 g	100 ml	100 ml	4 g

^ **Information shaded in grey in the table:** relates to dosage information for patients weighing less than 33 kg which is not applicable to Accord product.

^^ Risk factors for hepatotoxicity include (but are not limited to) hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione) and dehydration.

* **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.

*** **Patients weighing less will require smaller volumes.**

Irrespective of the weight:
- **The minimum interval between each administration must be at least 4 hours.**
- **The minimum interval between each administration in patients with severe renal insufficiency (creatinine clearance less than 30 ml/min) must be at least 6 hours.**
- **No more than 4 doses to be given in 24 hours.**

The paracetamol solution is administered as a 15-minute intravenous infusion.

Please note: **Paracetamol 10 mg/ml solution for Infusion 100 ml vials are restricted to patients (adults, adolescents and children) weighing more than 33 kg**

Please adhere to the following guidance when dispensing for patients weighing ≤ 10 kg:
- The glass vial of Paracetamol 10 mg/ml solution for Infusion should not be hung as an infusion due to the small volume of the medicinal product to be administered in this population.
- The volume to be administered should be withdrawn from the vial and diluted in a 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Paracetamol 10 mg/ml solution for Infusion into nine volumes diluent) and administered over 15 minutes.
- A 5 or 10 ml syringe should be used to measure the dose as appropriate for the weight of the child and the desired volume. However, this should never exceed 7.5 ml per dose.
- The user should refer to the product information for dosing guidelines.

To remove solution, use a 0.8 mm needle (21 gauge needle) and vertically perforate the stopper at the spot specifically indicated.

Paracetamol 10 mg/ml solution for Infusion dosing guide

Paracetamol 10 mg/ml solution for Infusion 100 ml vials are restricted to patients (adults, adolescents and children) weighing more than 33 kg.
Doses in grey are for informative purposes only.

Patient Weight (kg)	Dose per administration (mg)	Volume per administration (ml)
1	7.50	0.75
2	15.00	1.50
3	22.50	2.25
4	30.00	3.00
5	37.50	3.75
6	45.00	4.50
7	52.50	5.25
8	60.00	6.00
9	67.50	6.75
10	75.00	7.50
11	165.00	16.50
12	180.00	18.00
14	210.00	21.00
16	240.00	24.00
18	270.00	27.00
20	300.00	30.00
22	330.00	33.00
24	360.00	36.00
26	390.00	39.00
28	420.00	42.00
30	450.00	45.00
32	480.00	48.00
33	495.00	49.50
34	510.00	51.00
36	540.00	54.00
38	570.00	57.00
40	600.00	60.00
42	630.00	63.00
44	660.00	66.00
46	690.00	69.00
48	720.00	72.00
50	750.00	75.00
> 50	1000.00	100.00

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