

# Paracetamol Actavis Solution for Infusion

## Caution in Use: Risk of Medication Errors

### Important information about Paracetamol Actavis 10 mg/ml Solution for Infusion.

The use of Paracetamol Actavis 100 ml vials is restricted to patients (adults, adolescents and children) weighing more than 33 kg.

This poster has been prepared to give guidance on how to prevent medication errors in dispensing Paracetamol 10 mg/ml in all patient groups even though Paracetamol Actavis is not indicated for patients weighing less than 33 kg.

#### Risk of Medication Errors

Take care when dispensing Paracetamol Actavis 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.

**Each 1 ml of Paracetamol Actavis Solution for Infusion contains 10 mg of paracetamol. Paracetamol Actavis is only available in 100 ml bottle, containing 1000 mg of paracetamol.**

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

Dosing based on patient weight is presented in the table below:

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

<sup>^</sup> Information shaded in grey in the table: relates to dosage information for patients weighing less than 33 kg which is not applicable to Actavis product.

\* 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 Actavis 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 Actavis 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 Actavis 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 Actavis 10 mg/ml dosing guide

**Paracetamol Actavis 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