Paracetamol

10 mg/ml solution for infusion

Therapeutic indications:[1]

- Short-term treatment of moderate pain, especially following surgery
- Short-term treatment of fever

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.

Caution: Risk of overdose with Paracetamol 10 mg/ml solution for infusion in particular in children resulting from errors of administration.

The administered dose depends on the weight of the patient.
Depending on the child's weight, the volumes administered can be very low.

Administration protocol

Posology	Newborn infants, infants and children ≤ 10 kg	Children > 10 kg and ≤ 33 kg	Children, adolescents and adults > 33 kg and ≤ 50 kg	Adolescents and adults > 50 kg and no additional risk factors for hepatotoxicity	Adolescents and adults > 50 kg with additional risk factors for hepatotoxicity
Dose	7.5mg/kg i.e. 0.75ml/kg	15 mg/kg i.e. 1.5 ml/kg	15 mg/kg i.e. 1.5 ml/kg	1000 mg i.e. 1 Ecoflac® plus 100 ml	1000 mg i.e. 1 Ecoflac® plus 100 ml
	No more than 4 times a day of 7.5mg/kg	No more than 4 times a day of 15 mg/kg	No more than 4 times a day of 15 mg/kg	No more than 4 times a day of 1000 mg	No more than 4 times a day of 750 mg
Min interval	Minimal interval between each administration: 4 hours				
Max per 24 h	30mg/kg (without exceeding 300mg)	60 mg/kg (without exceeding 2000 mg)	60 mg/kg (without exceeding 3000 mg)	4000 mg	3000 mg
Presentation	10ml Mini Plasco®: 1ml = 10mg for patients up to 10kg 	50ml Ecoflac® plus: 1ml = 10mg for patients 10-33kg 		100 ml Ecoflac® plus: 1 ml = 10 mg for patients > 33 kg 	

Example (up to 10 kg)

Weight	Dose to be administered up to 4 times a day		Max dose per 24 hours	
2 kg	15 mg	1.5 ml	60 mg	6 ml
4 kg	30 mg	3.0 ml	120 mg	12 ml
6 kg	45 mg	4.5 ml	180 mg	18 ml
8 kg	60 mg	6.0 ml	240 mg	24 ml
10 kg	75 mg	7.5 ml	300 mg	30 ml

- In children with low weights paracetamol can be diluted in a 0.9 % sodium chloride solution or a 5 % glucose solution up to one tenth
- In case of dilution, chemical and physical stability of solution has been demonstrated at 23°C over 48 hours
- Remember that close monitoring is needed notably at the end of the infusion, in order to avoid air embolism

Detailed information can also be found in the current Summary of Product Characteristics (SmPC). Further a letter for health care professionals is provided on www.bbraun.ie and a dose calculator is also available.

References: [1] SmPC Paracetamol

Suspected adverse drug reactions should be reported to the Health Products Regulatory Authority via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie.
This information may also be reported directly to B. Braun via telephone at (01)7091800 or email at info.ie@bbraun.com.

Paracetamol
10 mg/ml solution for infusion

Prescribing information

Qualitative and quantitative composition

1 ml solution for infusion contains 10mg paracetamol.
Each 10ml ampoule contains 100mg paracetamol.
Each 50 ml bottle contains 500 mg paracetamol.
Each 100 ml bottle contains 1000 mg paracetamol.

Excipient(s) with known effect: Sodium 1.22 mg/ml.

List of excipients:
Mannitol, Hydroxyethyl starch, Sodium acetate trihydrate, Sodium citrate dihydrate, Acetic acid glacial (for pH adjustment), Water for injections

Indications
- Short-term treatment of moderate pain especially following surgery,
- 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.

Contraindications
- Hypersensitivity to paracetamol, propacetamol hydrochloride (prodrug of paracetamol) or to any of the excipients.
- Cases of severe hepatocellular insufficiency.

Undesirable effects
As with all paracetamol products, adverse drug reactions are rare (≥ 1/10 000 to <1/1 000) or very rare (<1/10 000). They are described below:

Blood and lymphatic system disorders: Very rare: Thrombocytopenia Leucopenia, Neutropenia

Immune system disorders: Very rare: Hypersensitivity reaction.[1]
Cardiac disorders: Not known: Tachycardia[2]
Vascular disorders: Rare: Hypotension, Not known: Flushing[2]
Hepatobiliary disorders: Rare: Increased levels of hepatic transaminases
Skin and subcutaneous tissue disorders: Not known: Pruritus[2], Erythema[2]
General disorders and administration site conditions: Rare: Malaise

Further information on particular undesirable effects:
(1) Very rare cases of hypersensitivity reactions ranging from simple skin rash or urticaria to anaphylactic shock have been reported and require discontinuation of treatment.
(2) Isolated cases

Frequent adverse reactions at injection site have been reported during clinical trials (pain and burning sensation).

Special warnings and precautions for use
RISK OF MEDICATION ERRORS
Take care to avoid dosing errors due to confusion between milligram (mg) and milliliter (ml), which could result in accidental overdose and death.

Prolonged or frequent use is discouraged. It is recommended that a suitable analgesic oral treatment will be used as soon as this route of administration is possible.

In order to avoid the risk of overdose, check that other medicines administered do not contain either paracetamol or propacetamol. The dose may require adjustment.

Doses higher than those recommended entail the risk of very serious liver damage. Clinical signs and symptoms of liver damage (including fulminant hepatitis, hepatic failure, cholestatic hepatitis, cytolytic hepatitis) are usually first seen after two days of drug administration with a peak seen, usually after 4 – 6 days. Treatment with antidote should be given as soon as possible.

Paracetamol should be used with caution in cases of:
- hepatocellular insufficiency
- severe renal insufficiency (creatinine clearance ≤ 30 ml/min)
- chronic alcoholism
- chronic malnutrition (low reserves of hepatic glutathione)
- dehydration
- 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.

As common practice in infusion therapy it is advisable to observe the patient for the occurrence of allergic reactions to the active ingredient or to the excipients (e.g. hydroxyethyl starch).

This medicinal product contains 61 mg (2.7 mmol) sodium in 50 ml and 122 mg (5.3 mmol) of sodium in 100 ml. To be taken into account for patients on a controlled sodium diet.

Pregnancy
Clinical experience of the intravenous administration of paracetamol is limited. However, epidemiological data from the use of oral therapeutic doses of paracetamol indicate no undesirable effects in pregnancy or on the health of the foetus / newborn infant.

Prospective data on pregnancies exposed to overdoses did not show any increase in the risk of malformation.

No reproductive studies with the intravenous form of paracetamol have been performed in animals. However, studies with the oral route did not show any malformation or foetotoxic effects.

Nevertheless, Paracetamol B. Braun should only be used during pregnancy after a careful benefit-risk assessment. In this case, the recommended posology and duration must be strictly observed.

Lactation
After oral administration, paracetamol is excreted into breast milk in small quantities. No undesirable effects on nursing infants have been reported. Consequently, Paracetamol B. Braun may be used in breast-feeding women.

Effects on ability to drive and use machines
Not relevant.

Shelf life
Unopened: 2 years.

In-use shelf-life (after opening): The infusion should commence immediately after connecting the container to the giving set.

After dilution: Paracetamol B. Braun can be diluted in 9 mg/ml (0.9%) sodium chloride solution for infusion or 50 mg/ml (5%) glucose solution for infusion up to one tenth. Chemical and physical in-use stability (including infusion time) in these solutions has been demonstrated for 48 hours at 23° C. In the case of diluting a 50 ml bottle, use the diluted solution within the hour following its preparation (infusion time included).

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

For prescription only!

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B BRAUN
SHARING EXPERTISE

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