

Summary of risk management plan for Paracetamol B. Braun 10 mg/ml solution for infusion (paracetamol)

This is a summary of the risk management plan (RMP) for Paracetamol B. Braun 10 mg/ml solution for infusion. The RMP details important risks of Paracetamol B. Braun 10 mg/ml solution for infusion, how these risks can be minimised, and how more information will be obtained about Paracetamol B. Braun 10 mg/ml solution for infusion 's risks and uncertainties (missing information).

Paracetamol B. Braun 10 mg/ml solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Paracetamol B. Braun 10 mg/ml solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Paracetamol B. Braun 10 mg/ml solution for infusion's RMP.

I. The medicine and what it is used for

Paracetamol B. Braun 10 mg/ml solution for infusion is authorised for short-term treatment of moderate pain, especially following surgery, and for 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 (see SmPC for the full indication). It contains paracetamol as the active substance and it is given by intravenous route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Paracetamol B. Braun 10 mg/ml solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Paracetamol B. Braun 10 mg/ml solution for infusion's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Paracetamol B. Braun 10 mg/ml solution for infusion, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Paracetamol B. Braun 10 mg/ml solution for infusion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Paracetamol B. Braun 10 mg/ml solution for infusion. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	Medication errors -overdose due to confusion between ml and mg in neonates and overdose in underweight adult patients
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Medication errors -overdose due to confusion between ml and mg in neonates and overdose in underweight adult patients	
Risk minimisation measures	<p><u>Routine risk minimisation measures</u></p> <p><i>SmPC section 4.2 and 4.4.</i></p> <p><i>Recommendation to take care when prescribing and administering Paracetamol B. Braun to avoid dosing errors due to confusion between milligram (mg) and millilitre (ml) in SmPC sections 4.2. and 4.4</i></p> <p><i>Recommendation that the dose to be administered and the bottle size to be used depend exclusively on the patient`s weight.</i></p> <p><i>Recommendation on treatment of overdose in SmPC section 4.9</i></p>

Important identified risk: Medication errors -overdose due to confusion between ml and mg in neonates and overdose in underweight adult patients

Pack size:

*The 10 ml ampoule is restricted to term newborn infants, infants and toddlers weighing up to 10 kg.
The 50 ml bottle is restricted to toddlers and children weighing more than 10 kg and up to 33 kg.
The 100 ml bottle is restricted to adults, adolescents and children weighing more than 33 kg.*

Legal status:

Prescription-only medicine

Additional risk minimisation measures:

*Direct Healthcare Professional Communication
Posters dedicated to the nurses' offices
Dose calculator*

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Paracetamol B. Braun 10 mg/ml solution for infusion.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Paracetamol B. Braun 10 mg/ml solution for infusion.