PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Paracetamol Baxter 10 mg/ml, solution for infusion (paracetamol)

This is a summary of the risk management plan (RMP) for Paracetamol Baxter 10 mg/ml solution for infusion (hereafter Paracetamol). The RMP provides details on the risks of Paracetamol and how these risks can be minimized.The summary of product characteristics (SmPC) and package leaflet (PL) for Paracetamol provide essential information to healthcare professionals and patients on how Paracetamol should be used.

New safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Paracetamol is authorized for a 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; refer to the SmPC for complete indication wording. It contains paracetamol as the active substance, and it is given by intravenous infusion.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

The important risks of Paracetamol, together with measures to minimize such risks, are outlined below. Measures to minimize 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 authorized pack size – the amount of medicine in a pack is chosen so as 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 minimize its risks.

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

In the case of Paracetamol, these measures are supplemented with *additional risk minimization measure* mentioned under the "summary of risks and missing information" section, below.

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

If important information that may affect the safe use of Paracetamol is not yet available, it is listed as 'missing information' below.

II.A List of important risks and missing information

Important risks of medicinal products are risks that need special risk management activities to further investigate or minimize 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 medicinal products. Potential risks are concerns for which an association with the use of the medicinal product is possible based on available data, but this association has not been established yet and needs to be further monitored. Missing information refers to information on the safety of the medicinal product that is currently missing and further information may need to be collected (e.g., on the long-term use of the medicine).

The important identified risk and missing information for Paracetamol are listed in the table below.

List of important risks and missing information	
Important identified risks	Medication error leading to an accidental overdose (overdose due to confusion between ml and mg in neonates and infants, and overdose in underweight adult patients)
Important potential risks	None
Missing information	Lack of data on use in premature neonates

II.B Summary of important risks and missing information

Important identified risk: Medication error leading to an accidental overdose (overdose due to confusion between ml and mg in neonates and infants, and overdose in underweight adult patients)	
Evidence for linking the risk to the medicine	Evidence source: post-marketing reports[1]
Risk factors and risk groups	*Pediatric patients* Due to the need for weight-based dosing of Paracetamol, children, especially neonates and infants, are at higher risk of an accidental overdose. Further, the prolonged half-life of paracetamol in neonates may increase the risk of overdose in this subpopulation. *Underweight adult patients* Due to the need for weight-based dosing of Paracetamol, adult patients at risk of accidental overdose are those weighting ≤ 50 kg.
Risk minimization measures	**Routine risk minimization measures:** *Paracetamol in glass vials and NPVC Viaflo bags* Discussed in SmPC sections 4.2 and 4.4. Discussed in PL sections 1, 3, and in the 'tear-off' section. Legal status: subject to medical prescription. *Paracetamol in glass vials* Paracetamol presentations are differentiated by color coding of container labels and aluminum caps. **Additional risk minimization measures:** *Paracetamol in glass vials* Dosing tool and poster. *Paracetamol in NPVC Viaflo bags* Dosing tool.
Missing information: Lack of data on use in premature neonates	
Risk minimization measures	**Routine risk minimization measures:** *Paracetamol in glass vials* Discussed in SmPC sections 4.2 and 5.2. Discussed in PL section 3 and in the 'tear-off' section. Legal status: subject to medical prescription. *Paracetamol in NPVC Viaflo bags* Discussed in SmPC section 5.2. Legal status: subject to medical prescription. **Additional risk minimization measures:** No additional risk minimization measures.

[1] SmPC of the reference medicinal product, Perfalgan by Bristol-Myers Squibb S.r.l., Italy

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligations of Paracetamol.

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

There are no studies required for Paracetamol.