Part VI: Summary of the risk management plan

Summary of risk management plan for Paracetamol 10mg/mL Solution for infusion

This is a summary of the risk management plan (RMP) for Paracetamol 10mg/mL Solution for infusion (hereinafter referred to as <Paracetamol>). The RMP details important risks of <Paracetamol>, how these risks can be minimised, and how more information will be obtained about <Paracetamol>'s risks and uncertainties (missing information).

<Paracetamol>'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <Paracetamol> should be used.

Important new concerns or changes to the current ones will be included in updates of <Paracetamol>'s RMP.

I. The medicine and what it is used for

<Paracetamol> is authorised for the 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 (see SmPC for the full indication). It contains paracetamol as the active substance and it is given by intravenous infusion.

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

Important risks of <Paracetamol>, together with measures to minimise such risks and the proposed studies for learning more about <Paracetamol>'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 case of <Paracetamol>, these measures are supplemented with *additional risk minimization 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*.

If important information that may affect the safe use of <Paracetamol> is not yet available, it is listed under "missing information", below.

II.A List of important risks and missing information

Important risks of <Paracetamol> 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>. 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	Hepatobiliary disorders and abnormal liver functions Drug interaction with anticoagulants Drug interaction with enzyme inducers Hypotension Medication errors (overdose due to confusion between mL and mg in neonates, and overdose in underweight adult patients) Hypersensitivity reactions (including severe cutaneous adverse reactions)
Important potential risks	None
Missing information	Neonates and premature neonates Pregnant and lactating women

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 minimization measures	Routine risk minimization measures: SmPC sections: 4.2, 4.4, 4.9 Dosing based on patient weight, detailed guidance on administration especially for patients weighting ≤10 kg and note on adjusting maximum daily dose according to other paracetamol containing products, ensuring the proper dose is communicated and dispensed and including both the total dose in mg and total dose in volume when writing prescriptions are included in SmPC section 4.2. Care to avoid dosing errors due to confusion between mg and mL, which could result in accidental overdose and death, is included in both 4.2 and 4.4 SmPC sections. Use of a suitable analgesic oral treatment as soon as this administration route is possible and check that other medicines administered do not contain either paracetamol or propacetamol is included in SmPC section 4.4. Clinical symptoms of liver damage and emergency measures in case of overdose are included in SmPC section 4.9. PL sections: 1, 2, 3, information intended for healthcare professionals only Communication with the doctor or pharmacist in case the patient is taking other medicines containing paracetamol or propacetamol is included in PL section 2. Dosing based on patient weight, detailed

	guidance on administration, note on adjusting maximum daily dose according to other paracetamol containing products and immediate communication with the doctor in case of overdose are included in PL section 3. Dosing based on patient weight, detailed guidance on administration especially for patients weighting ≤10 kg and note on adjusting maximum daily dose according to other paracetamol containing products is also included in PL section information intended for healthcare professionals only. Pack size: The 100 mL bottle is restricted to adults, adolescents and children weighing more than 33 kg. The 50 mL bottle is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg. Legal status: Prescription only medicine Labelling: 500 mg / 50 mL: Do not exceed the stated dose. For newborn infants, infants, toddlers and children weighing less than 33 kg 1000 mg / 100 mL: Do not exceed the stated dose. For adults, adolescents and children weighting more than 33kg. Additional risk minimization measures: Dosing guide strip Poster

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>.

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

There are no studies required for <Paracetamol>.