SUMMARY OF RISK MANAGEMENT PLAN FOR PARACETAMOL VERSION- 2.2

This is a summary of the risk management plan (RMP) for paracetamol, 10 mg/ml, solution for infusion. The RMP details important risks of paracetamol solution for infusion, how these risks can be minimized, and how more information will be obtained about paracetamol solution for infusions' 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, 10 mg/ml, solution for infusion is authorized for:
• 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. It contains paracetamol as an active substance and is administered intravenously in the form of solution for infusion (10 mg/ ml).

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

Important risks of Paracetamol solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Paracetamol 's 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 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 public (e.g. with or without prescription) can help to minimizes its risks.

Together, these measures constitute routine risk minimization measures.

In the case of paracetamol, solution for infusion, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important risks.

In addition to these measures, information about adverse events 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 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 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 error leading to overdose due to confusion between ml and mg
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Medication error leading to overdose due to confusion between ml and mg	
Risk minimisation measures	**Routine risk minimization measures:** • SmPC sections 4.2, 4.4 and 4.9PL section 3 • Legal status**:** Prescription only **Additional risk minimization measures:** • Poster and dosing guide strip

II.C Post-authorization development plan

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

No studies are conditions of the marketing authorization or specific obligations of Paracetamol solution for infusion.

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

Not applicable.