

6 SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for paracetamol oral and rectal formulations

This is a summary of the risk management plan (RMP) for paracetamol oral and rectal formulations. The RMP details important risks of paracetamol oral and rectal formulations, and how more information will be obtained about paracetamol oral and rectal formulation's risks and uncertainties (missing information).

Paracetamol oral and rectal formulation's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how paracetamol oral and rectal formulations should be used.

I. The medicine and what it is used for

Paracetamol oral and rectal formulations are authorised for the symptomatic treatment of mild to moderate pain and/or febrile conditions (see SmPC for the full indication). It contains paracetamol as the active substance and it is given by oral or rectal administration.

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

Important risks of paracetamol oral and rectal formulations, together with measures to minimise such 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 (eg, with or without prescription) can help to minimise its risks

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

II.A List of important risks and missing information

Important risks of paracetamol oral and rectal formulations are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. 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 (eg, on the long-term use of the medicine).

List of important risks and missing information

<i>Important identified risks</i>	Hepatotoxicity Hypersensitivity, including severe cutaneous adverse reactions Drug interaction with anticoagulants
<i>Important potential risks</i>	None
<i>Missing information</i>	Well-controlled clinical trials in pregnant and lactating women

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

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

Not applicable. There are no studies which are conditions of the marketing authorisation for paracetamol.

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

Not applicable. There are no other studies in the post-authorisation development plan for paracetamol.