

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for paracetamol

This is a summary of the risk management plan (RMP) for 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 it should be used.

Important new concerns or changes to the current ones will be included in updates of paracetamol Mylan's RMP.

I. The medicine and what it is used for

Paracetamol is authorised for symptomatic treatment of pain and fever in adults and children. It contains paracetamol as the active substance and it is given oral route.

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

Important risks of paracetamol, is together with measures to minimise such risks and the proposed studies for learning more about paracetamol Mylan '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 public (e.g. with or without prescription) can help to minimises its risks.

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

In addition to these measures, information about adverse events is collected continuously and is regularly analysed, 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 those risks that need special risk management activities to further investigate or minimise them, so that the medicinal product can be safely administered by patients. 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 the definite causal 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/use in special patient populations etc.);

Table 5 Part VI: Summary of safety concerns

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"> • Hepatotoxicity/ abnormal liver function (Patients with preexisting liver disease, chronic alcoholism, malnutrition, dehydration, underweight adults) • Overdose (accidental and intentional) and risk to exposure to multiple paracetamol-containing products • Drug interaction with anticoagulants • Drug interaction with enzyme inducers
Important potential risks	<ul style="list-style-type: none"> • Off-label use in children less than 16 years old.
Missing information	<ul style="list-style-type: none"> • Use during pregnancy and in utero exposure

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 authorization

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.