

Part VI: Summary of the risk management plan

Summary of risk management plan for Paracetamol/Ibuprofen Vale (ibuprofen/paracetamol)

This is a summary of the risk management plan (RMP) for Paracetamol/Ibuprofen Vale. The RMP details important risks of Paracetamol/Ibuprofen Vale, how these risks can be minimised, and how more information will be obtained about Paracetamol/Ibuprofen Vale's risks and uncertainties (missing information).

Paracetamol/Ibuprofen Vale 's summary of product characteristics (SPC) and its patient Information Leaflet (PIL) give essential information to healthcare professionals and patients on how Paracetamol/Ibuprofen Vale should be used.

I. The medicine and what it is used for

Paracetamol/Ibuprofen Vale is authorised for the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever (see SPC for the full indication).

It contains ibuprofen and paracetamol as the active substances and it is given orally.

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

Important risks of Paracetamol/Ibuprofen Vale, 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 (e.g. with or without prescription) can help to minimise its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed 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/Ibuprofen Vale 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. Identified risks are concerns for which there is sufficient proof of a link with the use of Paracetamol/Ibuprofen Vale. 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	None
Important potential risks	None
Missing information	None

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Paracetamol/Ibuprofen Vale.

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

There are no studies required for Paracetamol/Ibuprofen Vale.