

## **PART VI: Summary of the risk management plan**

This is a summary of the risk management plan (RMP) for the following products:

- PARACETAMOLO SKILLPHARMA 8 capsule rigide;
- PARACETAMOLO SKILLPHARMA 16 capsule rigide;
- PARACETAMOLO SKILLPHARMA 24 capsule rigide;
- PARACETAMOLO SKILLPHARMA 32 capsule rigide;
- PARACETAMOLO SKILLPHARMA 40 capsule rigide;

The RMP details important risks of PARACETAMOLO SKILLPHARMA, how these risks can be minimized, and how more information will be obtained about PARACETAMOLO SKILLPHARMA's risks and uncertainties (missing information).

PARACETAMOLO SKILLPHARMA's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how PARACETAMOLO SKILLPHARMA should be used.

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

### **I. The medicine and what it is used for**

Paracetamol oral formulations are authorised for the symptomatic treatment of mild to pain and fever or short-term treatment of febrile conditions in adults and children from 50 kg (aged from around 15 years).

It contains paracetamol as the active substance and is given by oral administration.

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

Important risks of paracetamol oral 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 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 (e.g., on the long term use of the medicine).

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"><li>• None.</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• None.</li></ul>
Missing information	<ul style="list-style-type: none"><li>• None.</li></ul>



## **II.B Summary of important risks**

Not applicable.

## **II.C Post-authorisation development plan**

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

There are no studies that are conditions of the marketing authorisation or specific obligation of PARACETAMOLO SKILLPHARMA.

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

There are no other studies in the post-authorisation development plan for PARACETAMOLO SKILLPHARMA.