

**Part VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

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

DOLZAN 's summary of product characteristics (SmPC) and their package leaflets give essential information to healthcare professionals and patients on how DOLZAN should be used.

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

DOLZAN is authorised for:

- Symptomatic treatment of mild to moderate pain and/or fever
- Symptomatic treatment of pain and inflammation in arthritic diseases (e.g. rheumatoid arthritis), degenerative arthritis conditions (e.g. osteoarthritis), and in painful swelling and inflammation after soft tissue injuries

(see SmPC for the full indication). It contains ibuprofen as the active substance and it is given by oral route.

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

Important risks of DOLZAN, together with measures to minimize such risks and the proposed studies for learning more about DOLZAN `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 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.

If important information that may affect the safe use of DOLZAN are not yet available, it is listed under 'missing information' below.

## **IIA. List of important risks and missing information**

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 DOLZAN. 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).

<b>Summary of safety concerns</b>	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

## **IIB. Summary of important risks**

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

## **IIC. 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 for DOLZAN.

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

There are no studies required for DOLZAN.