# Part VI: Summary of the risk management plan

## Summary of risk management plan for diclofenac diethylamine, 23.2 mg/g, Gel

Diclac Forte 23.2 mg/g, Gel

This is a summary of the risk management plan (RMP) for diclofenac diethylamine, 23.2 mg/g, gel. The RMP details important risks of diclofenac diethylamine, gel, how these risks can be minimized, and how more information will be obtained about diclofenac diethylamine, gel's risks and uncertainties (missing information).

Diclofenac diethylamine, gel's summary of product characteristics (SmPCs) and its package leaflets give essential information to healthcare professionals and patients on how diclofenac diethylamine, gel should be used.

Important new concerns or changes to the current ones will be included in updates of the diclofenac diethylamine, gel's RMP.

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

Diclofenac diethylamine, gel is authorized for:

Adults and adolescent aged 14 years and older

For symptomatic treatment of local pain of mild to moderate intensity in connection with muscular- and joint injury, e.g. sporting injuries.

The medicine is intended for short-term treatment.

It contains diclofenac diethylamine as an active substance and it is used topically as gel (23.2 mg/g).

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

Important risks of diclofenac diethylamine, gel, together with measures to minimize such risks and the proposed studies for learning more about diclofenac diethylamine, gel's risks, are outlined below.

Measures to minimize 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessment (according to European union reference dates (EURD) list) 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 diclofenac diethylamine, gel are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered/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 diclofenac diethylamine, gel. 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 |

There were no safety concerns applicable for this EU RMP based on the requirement to present only the important identified or potential risks and missing information linked to further pharmacovigilance activities or additional risk minimization measures in the EU.

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

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

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

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

There are no studies which are conditions of the marketing authorization or specific obligation of diclofenac diethylamine.

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

There are no studies required for diclofenac diethylamine.