Part VI: Summary of the risk management plan

Summary of risk management plan for Deflazacort Vital Pharma Nordic (Deflazacort)

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

Deflazacort Vital Pharma Nordic's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Deflazacort Vital Pharma Nordic should be used.

Important new concerns or changes to the current ones will be included in updates of Deflazacort Vital Pharma Nordic's RMP.

I. The medicine and what it is used for

Deflazacort Vital Pharma Nordic is authorised for Rheumatic and collagen diseases, Dermatologic diseases, Allergic diseases, Ocular pathology, Hepatic and gastrointestinal pathology and Kidney diseases. (see SmPC for the full indication). It contains deflazacort as the active substance and it is given by oral route of administration.

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

Important risks of Deflazacort Vital Pharma Nordic, together with measures to minimise such risks and the proposed studies for learning more about Deflazacort Vital Pharma Nordic'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, including PSUR assessment - 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 Deflazacort Vital Pharma Nordic is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Deflazacort Vital Pharma Nordic are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Deflazacort Vital Pharma Nordic.
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);

II.B Summary of important risks

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

Important identified risk

None

Important potential risk

None

Missing information

None

II.C Post-authorisation development plan

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

No studies are conditions of the marketing authorisation or specific obligation of Deflazacort Vital Pharma Nordic.

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

No studies are conditions of the marketing authorisation or specific obligation of Deflazacort Vital Pharma Nordic.