Part VI: Summary of the risk management plan

Summary of risk management plan for Dexacur 4 mg/ml solution for injection/infusion

This is a summary of the risk management plan (RMP) for Dexacur 4 mg/ml solution for injection/infusion. The RMP details important risks of this product, how these risks can be minimised, and how more information will be obtained about product's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Dexacur is authorized for:

- Cerebral oedema caused by brain tumour, neurosurgical procedures, brain abscess, bacterial meningitis
- Severe acute asthma attack
- Parenteral initial treatment of extensive acute severe skin diseases, such as erythroderma pemphigus vulgaris, acute eczema
- Initial parental treatment of active phases of collagenosis, such as systemic lupus erythematosus, especially visceral forms.
- Short-term co-adjuvant treatment during acute episodes or exacerbations of rheumatic diseases
- Severe infectious diseases with toxic conditions (e.g., tuberculosis, typhus, brucellosis) only with simultaneous anti-infective therapy.
- Prophylaxis and therapy of postoperative or cytostatic induced vomiting in antiemetic regimens

Local administration

- Intra and periarticular use in inflammatory diseases such as rheumatoid arthritis, osteoarthritis, periarthritis and epicondylitis.
- Non-bacterial tendovaginitis and bursitis, periarthropathies, insertion endopathies

This product contains dexametason as the active substance and it is taken by injection or infusion.

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

Important risks of Dexacur, together with measures to minimise such risks and the proposed studies for learning more about Dexacur'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.

II.A List of important risks and missing information

Important risks of Dexacur 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 dexametason. 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

There are no studies required for Dexacur.