Part VI: Summary of the risk management plan

Summary of risk management plan for *Dexamethasone 4 mg/ml solution for injection*

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

The summary of product characteristics (SmPC) for *Dexamethasone 4 mg/ml solution for injection* and its package leaflet give essential information to healthcare professionals and patients on how dexamethasone should be used.

I. The medicine and what it is used for

Dexamethasone 4 mg/ml solution for injection is authorised for the treatment of the following conditions: cerebral oedema, posttraumatic shock and prevention of posttraumatic acute respiratory distress syndrome (ARDS), Coronavirus disease 2019, anaphylactic shock, asthma attack, acute, severe skin diseases, autoimmune diseases such as lupus, active rheumatoid arthritis, severe infection disease, palliative therapy for malignant tumours, prophylaxis and therapy of postoperative or cytostatic-induced vomiting (see SmPC for the all licensed indications). It contains dexamethasone as the active substance and it is given by intravenous or intramuscular injection, intravenous infusion, subcutaneous injection or continuous infusion and as a local intraarticular or infiltration therapy.

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

Important risks of *Dexamethasone 4mg/ml solution for injection*, together with measures to minimise such risks and the proposed studies for learning more about *Dexamethasone 4mg/ml solution for injection* 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 a prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

If important information that may affect the safe use of *Dexamethasone 4mg/ml solution for injection* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Dexamethasone 4 mg/ml solution for injection* 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 *Dexamethasone 4 mg/ml solution for injection*. 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).

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• None
Missing information	• Safety in patients > 70 years old and in particular > 80 years old (COVID-19 indication) • Safety in pregnant women (COVID-19 indication)

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

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 of *Dexamethasone 4mg/ml solution for injection*.

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

There are no studies required for *Dexamethasone 4mg/ml solution for injection*.