Part VI: Summary of the risk management plan

Summary of risk management plan for Dexamethasone Phosphate Accord 4 mg/ml solution for injection (dexamethasone)

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

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

Important new concerns or changes to the current ones will be included in updates of Dexamethasone Phosphate Accord 4 mg/ml solution for injection' RMP.

I. The medicine and what it is used for

Dexamethasone Phosphate Accord 4 mg/ml Solution for injection is authorised for:

Systemic Use

Intravenous or Intramuscular administration:

Dexamethasone Phosphate Accord 4 mg/ml Solution for injection is recommended for systemic administration by intravenous or intramuscular injection when oral therapy is not feasible or desirable in the following conditions:

- Cerebral oedema caused by cerebral tumour, neurosurgical interventions, cerebral abscess, bacterial meningitis
- Posttraumatic shock and prevention of posttraumatic acute respiratory distress syndrome (ARDS)
- Coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) who require supplemental oxygen therapy.
- Anaphylactic shock (following initial epinephrine injection)
- Severe acute asthma attack

- Initial parenteral treatment of extensive, acute, severe skin diseases, such as erythroderma, pemphigus vulgaris, acute eczema
- Initial parenteral treatment of autoimmune diseases, such as systemic lupus erythematosus (in particular visceral forms)
- Active rheumatoid arthritis with a severe progressive course, e.g. rapidly destructive forms and/or with extraarticular manifestations
- Severe infectious diseases with toxic states (e.g. tuberculosis, typhus, brucellosis) only with appropriate anti-infective therapy
- Palliative therapy for malignant tumours
- Prophylaxis and therapy of postoperative or cytostatic-induced vomiting in the context of antiemetic regimens

Subcutaneous administration

- Palliative therapy for malignant tumours and prevention and treatment of chemotherapy-induced nausea and vomiting (CINV)

In palliative care, patients receiving corticosteroids for symptoms such as fatigue, anorexia, refractory nausea and vomiting or adjuvant analgesia and symptomatic treatment of cord compression or raised intracranial pressure, Dexamethasone Phosphate Accord 4 mg/ml Solution for injection may be administered subcutaneously as an alternative to the oral route when the latter is unacceptable or no longer feasible.

Local administration:

- Intraarticular injections for persistent inflammation in one or several joints after general treatment of chronic inflammatory joint disease, activated arthrosis, acute forms of periarthropathia humeroscapularis
- Infiltration therapy (when strictly indicated) for non-bacterial tendovaginitis and bursitis, periarthropathy, insertional tendinopathy.

It contains dexamethasone phosphate as the active substance and given by Intravenous or Intramuscular, Subcutaneous administration and Local administration (Intraarticular injections, Infiltration therapy) routes.

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

Important risks of Dexamethasone Phosphate Accord 4 mg/ml solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Dexamethasone Phosphate Accord 4 mg/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 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 Dexamethasone Phosphate Accord 4 mg/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 Phosphate Accord 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 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 Dexamethasone Phosphate Accord 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);

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 authorization or specific obligation of Dexamethasone Phosphate Accord 4 mg/ml solution for injection.

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

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