

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

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

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

Important new concerns or changes to the current ones will be included in updates of dexamethasone phosphate 4 mg/mL solution for injection's RMP.

I. The medicine and what it is used for

Dexamethasone phosphate 4 mg/ml solution for injection is authorised:

- for use in certain endocrine and non-endocrine disorders responsive to corticosteroid therapy
- in the treatment of 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

(see SmPC for the full indication).

It contains dexamethasone phosphate as the active substance and it is given for systemic administration by intravenous or intramuscular injection or by subcutaneous administration.

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

Important risks of Dexamethasone phosphate 4 mg/ml solution for injection, together with measures to minimise such risks, are outlined below.

Measures to minimise the risks identified for the medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package insert addressed to 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 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 4 mg/ml solution for injection are risks that need special management activities to further investigate or minimise the risk, so that the medicinal product can be administered safely. 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 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.

List of important risks and missing information	
Important Identified Risks	<ul style="list-style-type: none"> • Growth retardation in children • Neurodevelopmental adverse events in pre-term neonates
Important Potential Risks	<ul style="list-style-type: none"> • Tumour lysis syndrome • Foetal development toxicity • Use during lactation
Missing Information	<ul style="list-style-type: none"> • 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 Dexamethasone phosphate 4 mg/ml solution for injection Product Information is aligned with 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 phosphate 4mg/ml solution for injection.

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

There are no studies required for dexamethasone phosphate 4mg/ml solution for injection.