

Part VI: Summary of the risk management plan

Summary of risk management plan for

Dexamethasone phosphate Kalceks 4 mg/ml solution for injection/infusion

(dexamethasone sodium phosphate)

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

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

Important new concerns or changes to the current ones will be included in updates of Dexamethasone phosphate Kalceks's RMP.

I. The medicine and what it is used for

Dexamethasone phosphate Kalceks 4 mg/ml solution for injection/infusion is indicated for systemic use in the following indication:

- Treatment and prophylaxis of cerebral oedema in brain tumours (postoperatively and after X-ray radiation) and after spinal cord trauma.
- States of anaphylactic shock (e.g. contrast medium reaction) in combination with adrenaline, antihistamines and appropriate volume replacement (caution: mixed syringes).
- Hypovolaemic and polytraumatic shock not responding to volume replacement, oxygen administration and correction of acidosis alone (shock lung prophylaxis).
- Status asthmaticus (only with concomitant sympathomimetics).
- Acute severe dermatosis (e.g. pemphigus vulgaris, erythroderma, Lyell's syndrome).
- Severe blood diseases (e.g. acute thrombocytopenic purpura, haemolytic anaemia, as concomitant medication as part of leukaemia treatments).
- As second-line treatment for acute adrenocortical insufficiency (Addisonian crisis).

Dexamethasone phosphate Kalceks is indicated 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.

Also Dexamethasone phosphate Kalceks 4 mg/ml solution for injection/infusion is indicated for local use in the following indication:

- Periarticular and infiltrative therapy, e.g. in peri-arthritis scapulohumeralis, epicondylitis, bursitis, tendovaginitis, styloiditis.

- Intraarticular injection, e.g. in rheumatoid arthritis, if individual joints are affected or respond inadequately to systemic treatment, accompanying inflammatory reactions in rheumatoid arthritis.
- Subconjunctival injection, e.g. for conjunctivitis, scleritis, iridocyclitis (caution: glaucoma).

It contains dexamethasone sodium phosphate as the active substance and it is given by intravenous, intramuscular, intraarticular, subconjunctival or local (infiltration) route of administration in concentration of 4.37 mg dexamethasone sodium phosphate per millilitre.

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

Important risks of Dexamethasone phosphate Kalceks, together with measures to minimise such risks and the proposed studies for learning more about risks of Dexamethasone phosphate Kalceks, 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 SPC 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 Kalceks 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 Kalceks 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 phosphate Kalceks. 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	<i>None</i>
Important potential risks	<i>None</i>
Missing information	<i>Safety in patients >70 years old and in particular >80 years old (COVID-19 indication)</i>
	<i>Safety in pregnant women (COVID-19 indication)</i>

II.B Summary of important risks

Missing information: Safety in patients >70 years old and in particular >80 years old (COVID-19 indication)	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 5.1. Prescription only medicine. Additional risk minimisation measures: None.

Missing information: Safety in pregnant women (COVID-19 indication)	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6. PL section 2. Prescription only medicine. Additional risk minimisation measures: None.

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 Kalceks.

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

There are no studies required for Dexamethasone phosphate Kalceks.