Part VI: Summary of the risk management plan

Summary of risk management plan for Xadamin (dexamethasone), tablets

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

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

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

I. The medicine and what it is used for

Xadamin is authorised for:

- Conditions in which the anti-inflammatory and immunosuppressive effect of the corticosteroids is desirable. Especially for intensive treatment for a shorter time.
- Cerebral oedema or increased intracranial pressure due to brain tumour
- In the treatment of cancer mammae, ovarii, prostatae or testis when the effect of the corticosteroids is desirable.
- Prophylaxis of emesis induced by emetogenic chemotherapy.
- Diagnostic test of the pituitary and adrenal cortex function
- Xadamin 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.

(see SmPC for the full indication)

It contains dexamethasone as the active substance and it is given orally.

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

Important risks of Xadamin, together with measures to minimise such risks and the proposed studies for learning more about Xadamin risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- 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 Xadamin is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Xadamin 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 Xadamin. 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

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 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 and PL section 2 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 Xadamin.

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

There are no studies required for Xadamin.