Summary of risk management plan for DEXAMETHASONE PANPHARMA 4mg/mL, solution for injection (dexamethasone phosphate)

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

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

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

I. The medicine and what it is used for

When used as systemic administration, DEXAMETHASONE PANPHARMA is authorised for the general indications of oral corticosteroids when the parenteral route is necessary as oral treatment is impossible (vomiting, gastric aspiration, consciousness disorders).

It is also authorised for conditions requiring a rapid therapeutic effect including allergies (severe angioedema in addition to antihistamines, anaphylactic shock in addition to adrenalin), infections (severe infections with toxic conditions e.g. tuberculosis, typhoid, brucellosis only with concomitant anti-infective therapy) and neurological conditions (cerebral oedema triggered by brain tumour, neurosurgery, brain abscess, bacterial meningitis).

It is also used as a treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) with difficulty breathing and need of oxygen therapy.

When used as topical administration, DEXAMETHASONE PANPHARMA has the same indications as topical corticosteroids where the condition warrants a strong local concentration. It includes rheumatological conditions requiring infiltration therapy for non-bacterial tendovaginitis and bursitis, periarthropathies, insertion endopathies.

See SmPC for full indication.

It contains dexamethasone phosphate as the active substance and it is given by systemic administration (intravenous or intramuscular injection) or by topical administration (local infiltration).

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

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

Measures to minimise the risks are:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- The medicine's legal status — prescription only medicine.

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

II.A List of important risks and missing information

Important risks of DEXAMETHASONE PANPHARMA 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 PANPHARMA. 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 longterm use of the medicine).

List of important risks and missing information	
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.

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 DEXAMETHASONE PANPHARMA.

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

There are no studies required for DEXAMETHASONE PANPHARMA.