Part VI: Summary of the risk management plan

Summary of risk management plan for [Paliperidone] 25mg, 50 mg, 75 mg, 100

mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe

This is a summary of the risk management plan (RMP) for [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe risks and uncertainties (missing information).
[Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe should be used.

I. The medicine and what it is used for

[Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. It contains paliperidone as the active substance and it is given by injection.

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

Important risks of [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe, together with measures to minimise such risks and the proposed studies for learning more about [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe's risks, are outlined below.

Measures to minimise the known risks of this [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe include:

- 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.

If important information that may affect the safe use of [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe is not yet available, it is listed under the 'missing information' below.

II.A List of important risks and missing information

Important risks of [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe 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 [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Exposure during pregnancy

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 authorisation or specific obligation of [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe.

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

There are no studies required for [Paliperidone] 25mg, 50 mg, 75 mg, 100 mg, 150 mg, 150 mg/100 mg, prolonged release suspension for injection in pre-filled syringe.