Part VI: Summary of the risk management plan for Esketamine Orifarm

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

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

I. The medicine and what it is used for

Esketamine Orifarm is authorised for induction of general anaesthesia, analgesic supplementation of regional and local anaesthesia and analgesia in emergency medicine (see SmPC for the full indication). It contains esketamine as the active substance and it is given as an injection/infusion.

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

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

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish, Swedish and Finnish Medicines Agency.
- The medicine's is prescription only medicine and must be prescribed by a doctor.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Esketamine Orifarm 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 Esketamine Orifarm. 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	• Anaphylactic reactions • Blood pressure increased • Emergence reactions • Intraocular pressure increased

List of important risks and missing information	
	• Laryngospasm
Important potential risks	• Abuse and dependence • Urinary tract-related adverse events, including cystitis
Missing information	None

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 Esketamine Orifarm.

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

There are no studies required for Esketamine Orifarm.