Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for Miprosed (midazolam) 5mg/ml Drank.

The RMP details important risks of Miprosed (midazolam) 5mg/ml Drank, show these risks can be minimized, and how more information will be obtained about Miprosed 5mg/ml Drank's risks and uncertainties (missing information).

Miprosed 5mg/ml Drank's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Miprosed 5mg/ml Oral Solution should be used.

I. The medicine and what it is used for

Miprosed 5mg/ml Oral solution is authorised for children aged 6 months to 14 years for sedation and anxiolysis prior to diagnostic, surgical, therapeutic or endoscopic procedures and as premedication before induction of anaesthesia in the EEA (see SmPC for the full indication). It contains midazolam as the active substance and it is given by the oral route.

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

Important risks of Miprosed 5mg/ml Drank, together with measures to minimise such risks and the proposed monitoring for establishing more information about Miprosed 5mg/ml Oral Solution's risks, 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 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 it provides a course of treatment for s single person undergoing a single surgical / diagnostic procedure
- 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.

II.A List of important risks and missing information

Important risks of Miprosed 5mg/ml Drank 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 Midazolam 5mg/ml Oral Solution. 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	• Pharmacokinetic Interactions with CYP3A4 inhibitors or inducers • Pharmacodynamic Interactions with other central nervous system depressants • Use in patients with hepatic impairment, renal impairment, respiratory/cardiac insufficiency or in chronically ill or debilitated patients • Impaired ability to perform activities requiring mental alertness or physical coordination • Overdose • Hypersensitivity/allergic reactions • Anterograde amnesia • Paradoxical reactions
Important potential risks	• Abuse/misuse for illegal purposes • Potential for IV or IM administration • Medication error
Missing information	• Use during pregnancy and breast-feeding • Use in children less than 6 months old

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to other medicinal products containing Midazolam for oral use

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 Miprosed Drank.

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

There are no studies required for Miprosed Drank.