Summary of the risk management plan for Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution (10 mg/2 mL)

This is a summary of the risk management plan (RMP) for Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution.

The RMP details important risks of Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution**,** how these risks can be minimized, and how more information will be obtained about Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution´s risks, and uncertainties (missing information).

Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution´s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Midazolam 2.5 mg & 5mg & 7.5 mg & 10 mg oromucosal solution should be used.

I. The medicine and what it is used for

Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution is authorized for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years) (see SmPC for the full indication). It contains Midazolam as the active substance, and it is given by oral route.

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

Important risks of Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution together with measures to minimise such 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 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 Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution is noy yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution 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 Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal 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

Summary of safety concerns	
Important identified risks	-Respiratory depression -CNS depression -Interactions with other CNS drugs -Apnoea -Respiratory or cardiac arrest -Anterograde amnesia -Praradoxical reactions -Nausea and vomiting -Pruritis
Important potential risks	-Physical dependence -Off label use -Abuse potential/diversion -Buccal irritation -Asphyxiation/aspiration -Oral/facial trauma -Drug facilitated sexual assault
Missing information	-Patients with impaired renal function -Patients with impaired hepatic function -Pregnant or lactating women

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 Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution.

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

There are no studies required for Midazolam 2.5 mg & 5 mg & 7.5 mg & 10 mg oromucosal solution.