Summary of the risk management plan for Midazolam Medical Valley 2.5, 5, 7.5 and 10 mg oromucosal solution (5 mg/mL) (midazolam)

This is a summary of the risk management plan (RMP) for Midazolam Medical Valley 2.5, 5, 7.5 and 10 mg oromucosal solution. The RMP details important risks of Midazolam Medical Valley 2.5, 5, 7.5 and 10 mg oromucosal solution, how these risks can be minimized, and how more information will be obtained about Midazolam Medical Valley 2.5, 5, 7.5 and 10 mg oromucosal solution´s risks, and uncertainties (missing information).

Midazolam Medical Valley 2.5, 5, 7.5 and 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 Medical Valley 2.5, 5, 7.5 and 10 mg oromucosal solution should be used.

I. The medicine and what it is used for

Midazolam Medical Valley 2.5, 5, 7.5 and 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 Medical Valley 2.5, 5, 7.5 and 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*.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, 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 Midazolam Medical Valley 2.5, 5, 7.5 and 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 Medical Valley 2.5, 5, 7.5 and 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 Medical Valley 2.5, 5, 7.5 and 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 risk and missing information	
Important identified risks	• None
Important potential risks	• Aspiration/aspiration pneumonia • Medication errors
Missing information	• Use in children less than 6 months of age

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 Medical Valley 2.5, 5, 7.5 and 10 mg oromucosal solution.

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

There are no studies required for Midazolam Medical Valley 2.5, 5, 7.5 and 10 mg oromucosal solution.