# Part VI: Summary of the risk management plan

**Summary of risk management plan for Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation (Desflurane)**

This is a summary of the risk management plan (RMP) for Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation. The RMP details important risks of Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation, how these risks can be minimised, and how more information will be obtained about Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation's risks and uncertainties (missing information).

Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalationshould be used.

Important new concerns or changes to the current ones will be included in updates of Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation's RMP.

## I. The medicine and what it is used for

Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation is authorised for induction and/or maintenance of anaesthesia for inpatient and outpatient surgery in adults and for the maintenance of anaesthesia in infants and children (see SmPC for the full indication). It contains desflurane as the active substance and it is given by inhalation.

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

Important risks of Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation, together with measures to minimise such risks and the proposed studies for learning more about Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation'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 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 Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation is not yet available, it is listed under 'missing information' below.

### *II.A List of important risks and missing information*

Important risks of Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation 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 Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation. 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 | Perioperative hyperkalemia<br>Cardiac arrhythmias<br>Myocardial ischemia in patients with a history of coronary artery disease<br>Laryngospasm during induction and maintenance of anaesthesia in non-intubated children |
| Important potential risks | Increased intracranial pressure in patients with space occupying lesions |
| Missing information | Use in pregnant and lactating women during labour and vaginal delivery<br>Developmental disorder in children following intrauterine exposure or with paediatric use |

### *II.B Summary of important risks*

The safety information in the current 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 obligations of Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation.

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

There are no studies required for Desfluran Piramal 100 % (v/v) Flüssigkeit zur Herstellung eines Dampfs zur Inhalation.