PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Zomig Nasal (zolmitriptan)

This is a summary of the RMP for Zomig Nasal. The RMP details important risks of Zomig Nasal, how these risks can be minimized, and how more information will be obtained about Zomig Nasal's risks and uncertainties (missing information).

Zomig Nasal's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Zomig Nasal should be used.

I. The medicine and what it is used for

Zomig Nasal is authorised in adults and adolescents aged 12 years and older for the acute treatment of migraine headache with or without aura and in adults for the acute treatment of cluster headache (see SmPC for the full indication). It contains zolmitriptan as the active substance and it is given by nasal administration.

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

There are no important risks or missing information for Zomig Nasal requiring additional risk minimisation measures or additional pharmacovigilance activities, as defined in GVP Module V. Important risks are those that require specific risk management activities to further investigate or minimise the risk to ensure safe use of the product

General measures to minimize 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 authorized 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 minimize 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*.

II.A List of important risks and missing information

Important risks of Zomig Nasal are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Zomig Nasal. 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	none
Important potential risks	none
Missing information	none

II.B Summary of important risks

There are no important identified risks, important potential risks or areas of missing information for Zomig Nasal.

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 Zomig Nasal.

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

There are no studies required for Zomig Nasal.