

Summary of Risk Management Plan

This is a summary of the risk management plan (RMP) for Zolmitriptan Jubilant 2.5 mg/5 mg film-coated tablets and 2.5 mg/5 mg orodispersible tablets. The RMP details important risks of Zolmitriptan Jubilant, how these risks can be minimised, and how more information will be obtained about Zolmitriptan risks and uncertainties (missing information).

Zolmitriptan Jubilant summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Zolmitriptan Jubilant 2.5 mg/5 mg film-coated tablets and 2.5 mg/5 mg orodispersible tablets should be used.

I. The medicine and what it is used for

Acute treatment of migraine headache with or without aura.

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

Important risks of Zolmitriptan Jubilant, together with measures to minimise such risks for learning more about Zolmitriptan Jubilant 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.

II.A List of important risks and missing information

Important risks of Zolmitriptan Jubilant 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 Zolmitriptan Jubilant.

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).

Summary of safety concerns	
Important identified risks	• None

Summary of safety concerns	
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the Product Information is aligned to the reference medicinal products (Zomig film-coated tablet, AstraZeneca AB and Zomig Rapimelt orodispersible tablets, Grunenthal Ltd UK)

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 Zolmitriptan Jubilant.

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

There are no studies required for Zolmitriptan Jubilant.