

Part VI: Summary of the risk management plan for Jorveza® 0.5mg/1mg orodispersible tablets

This is a summary of the risk management plan (RMP) for Jorveza® 0.5mg/1mg orodispersible tablets. The RMP details important risks of Jorveza® 0.5mg/1mg orodispersible tablets, how these risks can be minimised and how more information will be obtained about risks and uncertainties (missing information) associated with the use of the product.

Jorveza® 0.5mg/1mg orodispersible tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Jorveza® 0.5mg/1mg orodispersible tablets should be used.

I. The medicine and what it is used for

Jorveza® 0.5mg/1mg orodispersible tablets are authorised for the treatment of eosinophilic esophagitis (EoE) in adults (older than 18 years of age).

It contains budesonide as the active substance and it is given by oral route of administration.

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

Important risks of Jorveza® 0.5mg/1mg orodispersible tablets, together with measures to minimise such risks and the proposed study for learning more about Jorveza®'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 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.

II.A List of important risks and missing information

None

II.B Summary of important risks

None

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 Jorveza® 0.5mg/1mg orodispersible tablets.

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

Not applicable.