

Part VI: Summary of the risk management plan

Summary of risk management plan for MAGALDRATO DOC

This is a summary of the risk management plan (RMP) for MAGALDRATO DOC. The RMP details important risks of MAGALDRATO DOC, how these risks can be minimised, and how more information will be obtained about MAGALDRATO DOC's risks and uncertainties (missing information).

MAGALDRATO DOC's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how MAGALDRATO DOC should be used.

Important new concerns or changes to the current ones will be included in updates of MAGALDRATO DOC's RMP.

I. The medicine and what it is used for

MAGALDRATO DOC is authorised for treatment of duodenal and gastric ulcer and oesophagitis reflux; symptomatic DOC treatment of gastritis and gastro-duodenitis of various etiologies characterized by hyperacidity in adults and in adolescents over 12 years of age.

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

Important risks of, MAGALDRATO DOC together with measures to minimise such risks and the proposed studies for learning more about MAGALDRATO DOC'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.

If important information that may affect the safe use of MAGALDRATO DOC is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of MAGALDRATO DOC are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 MAGALDRATO DOC. 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	<ul style="list-style-type: none">- Use in renal failure- Nervous system disorders (including neurotoxicity and encephalopathy)
Important potential risks	<ul style="list-style-type: none">- Pneumonia in patients with artificial ventilation- Drug interaction:
Missing information	<ul style="list-style-type: none">- Pregnancy and breastfeeding

II.B Summary of important risks

As magaldrate is widely used since more than 10 years in Europe; it has a well-established use with recognized efficacy, and an acceptable level of safety.

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 MAGALDRATO DOC.

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

There are no studies required for MAGALDRATO DOC.