PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for esomeprazole

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

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

I. The medicine and what it is used for

Esomeprazole is authorised for the treatment of:

Austria (*Esomeprazole Arcana 20 mg magensaftresistente Hartkapseln and Esomeprazole Arcana 20 mg magensaftresistente Hartkapseln*)

Adults:
Gastro-oesophageal Reflux Disease (GORD)
- Treatment of erosive reflux oesophagitis
- Long-term management of patients with healed oesophagitis to prevent relapse
- Symptomatic treatment of gastro-esophageal reflux disease (GORD)

In combination with an appropriate antibacterial therapeutic regimen for the eradication of Helicobacter pylori and
- healing of *Helicobacter pylori* associated duodenal ulcer and
- prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers.

Patients requiring continued NSAID therapy
Healing of gastric ulcers associated with NSAID therapy.
Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk.

Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers.

Treatment of Zollinger Ellison Syndrome
Adolescents from the age of 12 years
Gastro-oesophageal Reflux Disease (GORD)
- treatment of erosive reflux oesophagitis
- long-term management of patients with healed oesophagitis to prevent relapse.
- symptomatic treatment of gastro-oesophageal reflux disease (GORD)

France (*Esomeprazole Mylan Conseil 20 mg, gélule gastro-résistante*)

Esomeprazole is indicated for the short-term treatment of symptoms of gastroesophageal reflux (eg, heartburn and acid regurgitation) in adults.

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

Important risks of esomeprazole, together with measures to minimise such 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and is regularly analysed, 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 esomeprazole, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of esomeprazole are those risks that need special risk management activities to further investigate or minimise them, so that the medicinal product can be safely administered to patients. 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 esomeprazole. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but the definite causal 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/use in special patient populations etc.);

TABLE 4 PART VI: SUMMARY OF SAFETY CONCERNS

List of important risks and missing information	
Important identified risks	• Marked decrease in the number of white blood cells (Agranulocytosis) • (State of altered reactivity in which the body reacts with an exaggerated immune response to a foreign agent) Hypersensitivity reactions • Low magnesium blood levels (Hypomagnesaemia) • Feeling depressed (Depression) • Liver disorders (Hepatic reactions) • Potentially life-threatening rashes resulting from exposure to a drug (Severe cutaneous adverse reactions) • Inflammation of the kidney (Interstitial nephritis) • Breaking of the hip, wrist or spine bones (Fracture of the hip, wrist or spine) • Infection of the digestive tract caused by bacteria, viruses, or parasites (Gastrointestinal infections) • Alteration of the effects of a drug by reaction with another drug, such as blood thinning medicines, medicines used to treat convulsions, AIDS, heart conditions, rheumatoid arthritis, autoimmune disorders (Interaction with warfarin or other coumarine derivatives, Interaction with phenytoin, Interaction with atazanavir, Interaction with nelfinavir, Interaction with digoxin, Interaction with methotrexate, Interaction with tacrolimus and Interaction with clopidogrel)
Important potential risks	• Convulsion/seizure • Infection of the air sacs of the lungs (Pneumonia)
Missing information	• Use in pregnant or breastfeeding patients (Use in pregnant and lactating women) • Use in patients suffering from kidney disease (Use in patients with renal impairment)

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal

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 esomeprazole.

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

There are no studies required for esomeprazole.