Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Cyanocobalamin Glenmark (Cyanocobalamin)

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

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

I. The medicine and what it is used for

Cyanocobalamin Glenmark is authorised for

- Treatment of cobalamin deficiency due to malnutrition
- Long-term-treatment of cobalamin deficiency syndrome, for example due to malabsorption
- Oral treatment of pernicious anaemia and vitamin B_{12} deficiency with neurological symptoms, after rapid normalization of the B_{12}-assotiated biomarkers with parenterally administrated vitamin B_{12}.

In the case patients needing rapid normalization of vitamin B_{12}-associated biomarkers, a remission treatment should be performed with parenteral administration of vitamin B_{12}.

It contains cyanocobalamin as the active substance and it is given orally.

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

Important risks of Cyanocobalamin Glenmark, together with measures to minimise such risks and the proposed studies for learning more about Cyanocobalamin Glenmark 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 PL 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health Authority, 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 Cyanocobalamin Glenmark 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 Cyanocobalamin Glenmark. 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 risk(s)	• None
Important potential risk(s)	• None
Missing information	• None

II.B. Summary of important risk

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 Cyanocobalamin Glenmark.

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

There are no studies required for Cyanocobalamin Glenmark.