PART VI- Summary of the risk management plan

Summary of risk management plan for Vitamin D3 (Cholecalciferol)

This is a summary of the risk management plan (RMP) for Vitamin D3. The RMP details important risks of Vitamin D3 and how more information will be obtained about Vitamin D3's risks and uncertainties (missing information).

Vitamin D3's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Vitamin D3 should be used.

I. The medicine and what it is used for

Vitamin D3 is authorised for the treatment (20000 IU and 1000 IU) and prevention (1000 IU) of Vitamin D deficiency (see SmPC for the full indication). It contains Cholecalciferol as the active substance and it is given by oral route administration.

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

Important risks of Vitamin D3, together with measures to minimise such risks and the proposed studies for learning more about Vitamin D3'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 medicines 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 analyzed, 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 Vitamin D 20 000 IU and 1000 IU 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 Vitamin D 20 000 IU and 1000 IU. 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 Risks	None
Important Potential Risks	None
Missing Information	None

II.B Summary of important risks

Not applicable.

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 Vitamin D3.

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

There are no studies required for Vitamin D3.