Part VI: Summary of the risk management plan

Summary of risk management plan for calcium carbonate+cholecalciferol.

Calcium carbonate+cholecalciferol's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how calcium carbonate+cholecalciferol should be used.

I. The medicine and what it is used for

Calcium carbonate+cholecalciferol is authorised for prevention and treatment of vitamin D and calcium deficiency. Vitamin D and calcium supplement is used as an adjunct to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency. See the SmPC for the full indication. Calcium carbonate+cholecalciferol is the active substance and it is given by the oral route.

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

Not applicable. This version of the RMP was adapted to comply with the revised EMA Guidance on RMPs and associated RMP template revision. As such, there are no important identified or potential risks, or missing information associated with this medicine. The safety profile is well documented in the product labelling.

II.A List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

No important risks were identified for calcium carbonate+cholecalciferol.

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 any specific obligations for calcium carbonate+cholecalciferol.

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

There are no studies required for calcium carbonate+cholecalciferol.