Part VI: Summary of the risk management plan

Summary of risk management plan for ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA 70 mg/2,800 IU & ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA 70 mg/5,600 IU tablets

This is a summary of the risk management plan (RMP) for ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA 70 mg/2,800 IU & ALENDRONIC ACID/CHOLECALCIFEROL 70 mg/5,600 IU tablets (hereafter called ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA). The RMP details important risks of ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA, how these risks can be minimized, and how more information will be obtained about ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA's risks and uncertainties (missing information).

ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA should be used.

Important new concerns or changes to the current ones will be included in updates of ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA's RMP.

I. The medicine and what it is used for

ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA is authorised for the treatment of postmenopausal osteoporosis in women at risk of vitamin D insufficiency. It reduces the risk of vertebral and hip fractures (see SmPC for the full indication). It contains alendronic acid and cholecalciferol as the active substance and it is given by oral administration.

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

Important risks of ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA, together with measures to minimize such risks and the proposed studies for learning more about ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA's risks, a 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 ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA 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 ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA. 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	▪ Osteonecrosis of the jaw ▪ Oesophageal adverse experiences
Important potential risks	▪ Atypical femur fracture
Missing information	▪ Use in children and adolescents ▪ Use in patients with severe renal impairment ▪ Use in pregnancy and lactation

II.B Summary of important risks

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 ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA.

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

There are no studies required for ALENDRONIC ACID/CHOLECALCIFEROL MEDIPHA.