Part VI: Summary of the risk management plan

Summary of risk management plan for Alendronic acid/Cholecalciferol 70 mg/ 2,800 IU tablets and Alendronic acid/Cholecalciferol 70 mg/ 5,600 IU tablets (Alendronic acid and Cholecalciferol)

This is a summary of the risk management plan (RMP) for Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets. The RMP details important risks of Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets, how these risks can be minimised, and how more information will be obtained about Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablet's risks and uncertainties (missing information).

Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablet's RMP.

I. The medicine and what it is used for

Alendronic acid/Cholecalciferol is indicated for the treatment of postmenopausal osteoporosis in women at risk of vitamin D insufficiency. It reduces the risk of vertebral and hip fractures.

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

Important risks of Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablet, together with measures to minimise such risks and the proposed studies for learning more about Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablet'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 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 PSUR assessment and signal management activity, 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 Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets 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 (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets 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 Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets. 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	• 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.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 (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets.

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

There are no studies required for Alendronic acid/Cholecalciferol (70 mg/ 2,800 IU and 70 mg/ 5,600 IU) tablets.