

Part VI: Summary of the risk management plan

Summary of risk management plan for BISFOLID 200mg+40mg injectable solution (clodronic acid disodium salt tetrahydrate, lidocaine hydrochloride)

This is a summary of the risk management plan (RMP) for BISFOLID 200mg+40mg injectable solution, how these risks can be minimised, and how more information will be obtained about BISFOLID 200mg+40mg injectable solution's risks and uncertainties (missing information).

BISFOLID 200mg+40mg injectable solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how BISFOLID 200mg+40mg injectable solution should be used.

I. The medicine and what it is used for

Clodronic acid 200mg+40mg injectable solution with lidocaine is authorised for prevention and treatment of postmenopausal osteoporosis. It contains clodronic acid disodium salt tetrahydrate and lidocaine hydrochloride as the active substances and it is given by intramuscular route of administration.

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

Important risks of BISFOLID 200mg+40mg injectable solution, together with measures to minimise such risks and the proposed studies for learning more about BISFOLID 200mg+40mg injectable solution'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, 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 BISFOLID 200mg+40mg injectable solution are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 BISFOLID 200mg+40mg injectable solution. 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 • Eye disorders
Important potential risks	• Atrial fibrillation • Atypical femoral fractures • Osteonecrosis of the external auditory canal • Renal failure
Missing information	• Use during pregnancy and lactation

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the approved for the Reference Product Clasteon, developed by Abiogen Pharma (PSUSA/00010650/202202).

II.C Post-authorisation development plan

Not applicable.