

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for CLODRONATO DISODICO IBSA 100 mg + 33 mg solution for injection with lidocaine**

### **CLODRONATO DISODICO IBSA 200 mg + 40 mg solution for injection with lidocaine**

This is a summary of the Risk Management Plan (RMP) for CLODRONATO DISODICO IBSA 100 mg + 33 mg and 200 mg + 40 mg, solution for injection. The RMP details important risks of the product, how these risks can be monitored and minimized, and how more information will be obtained about CLODRONATO DISODICO IBSA >100 mg + 33 mg and 200 mg + 40 mg, solution for injection's risks and uncertainties (missing information).

CLODRONATO DISODICO IBSA 100 mg + 33 mg and 200 mg + 40 mg, solution for injection for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of CLODRONATO DISODICO IBSA's RMP.

#### **I. The medicine and what it is used for**

CLODRONATO DISODICO IBSA is authorised for:

- Tumor osteolysis
- Multiple myeloma
- Primary hyperparathyroidism
- Prevention and treatment of post-menopausal osteoporosis

((see SmPC. It contains clodronic acid with lidocaine <INN> as the active substance and it is given either intramuscular (im)).

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

Important risks of CLODRONATO DISODICO IBSA together with measures to minimise such risks and the proposed studies for learning more about CLODRONATO DISODICO IBSA'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 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 CLODRONATO DISODICO IBSA 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 CLODRONATO DISODICO IBSA. 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).

### ***II.B Summary of important risks***

| Summary of safety concerns |                                      |
|----------------------------|--------------------------------------|
| Important identified risks | None                                 |
| Important potential risks  | Atrial Fibrillation (clodronic acid) |
| Missing information        | None                                 |

### ***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 authorization or specific obligation of CLODRONATO DISODICO IBSA.

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

There are no other studies required for CLODRONATO DISODICO IBSA.