Summary of risk management plan for OSTEONORM (Disodium clodronate/Lidocaine)

This is a summary of the risk management plan (RMP) for OSTEONORM. The RMP details important risks of OSTEONORM, how these risks can be minimised, and how more information will be obtained about OSTEONORM 's risks and uncertainties (missing information).

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

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

0. The medicine and what it is used for

OSTEONORM is authorised for "Tumor osteolysis. Multiple myeloma. Primary hyperparathyroidism. Prevention and treatment of postmenopausal osteoporosis.". (see SmPC for the full indication).

It contains Disodium clodronate and Lidocaine as the active substance and it is given by intramuscular vials.

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

Important risks of OSTEONORM, together with measures to minimise such risks and the proposed studies for learning more about OSTEONORM'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.

If important information that may affect the safe use of OSTEONORM is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of OSTEONORM 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 OSTEONORM. 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 for Disodium clodronate	
Important identified risks	• Osteonecrosis of the mandible and / or jaw • Occurrence of osteonecrosis of the jaw after stopping treatment with clodronate • Increased risk of osteonecrosis of the jaw due to co-administration of clodronate and angiogenesis inhibitors. • Osteonecrosis of hip, femur and other locations, with exception of jaw and external auditory canal. • Osteonecrosis of the auditory canal • Atypical fractures of the femur
Important potential risks	• Atrial fibrillation
Missing information	• Use during pregnancy and lactation

List of important risks and missing information for Lidocaine	
Important identified risks	• Increased exposure due to accidental intravascular injection • Central nervous or cardiovascular reactions following accidental intravascular injection
Important potential risks	• None
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 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 OSTEONORM.

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

There are no studies required for OSTEONORM.