Part VI: Summary of the risk management plan

Summary of risk management plan for Zoledronic Acid SUN 5mg/100ml (Zoledronic acid)

This is a summary of the risk management plan (RMP) for Zoledronic Acid SUN 5mg/100ml. The RMP details important risks of Zoledronic Acid SUN 5mg/100ml and how more information will be obtained about Zoledronic Acid SUN 5mg/100ml's risks and uncertainties (missing information).

Zoledronic Acid SUN 5mg/100ml's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Zoledronic Acid SUN 5mg/100ml should be used.

Important new concerns or changes to the current ones will be included in updates of Zoledronic Acid SUN 5mg/100ml's RMP.

I. The medicine and what it is used for

Zoledronic Acid SUN 5mg/100ml is authorised for treatment of osteoporosis

- in post-menopausal women
- in adult men

at increased risk of fracture, including those with a recent low-trauma hip fracture.

Treatment of osteoporosis associated with long-term systemic glucocorticoid therapy

- in post-menopausal women
- in adult men

at increased risk of fracture.

Treatment of Paget's disease of the bone in adults.

It contains Zoledronic acid as the active substance and it is given by intravenous infusion.

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

Important risks of Zoledronic Acid SUN 5mg/100ml, together with measures to minimise such 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: prescription only medicine.

Together, these measures constitute routine risk minimisation measures.

In the case of Zoledronic Acid SUN 5mg/100ml, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks below.

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.

If important information that may affect the safe use of Zoledronic Acid SUN 5mg/100ml is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Zoledronic Acid SUN 5mg/100ml 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 Zoledronic Acid SUN 5mg/100ml. 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 (from Part II: Module SVIII)	
Important identified risks	Osteonecrosis of the jaw Atypical femoral fracture
Important potential risks	Teratogenicity
Missing information	None

II.B Summary of important risks

Important identified risk: Osteonecrosis of the jaw (ONJ)	
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.4, Section 4.8, and Package leaflet (PL) Section 2. Additional risk minimisation measures: Patient reminder card on ONJ.
Important identified risk: Atypical femoral fracture	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 and 4.8 Additional risk minimisation measures: None
Important potential risks: Teratogenicity	
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.3, Section 4.6, and Package leaflet Section 2. Additional risk minimisation measures: 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 authorisation or specific obligation of Zoledronic Acid SUN 5mg/100ml.

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

There are no studies required for Zoledronic Acid SUN 5mg/100ml.