Summary of risk management plan for

"Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"
(teriparatide)

This is a summary of the risk management plan (RMP) for "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen". The RMP details important risks of "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen", how these risks can be minimised, and how more information will be obtained about "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"risks and uncertainties (missing information).
"Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"should be used.

This summary of the RMP for "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen" should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen's RMP.

I. The medicine and what it is used for

"Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen" is indicated in adults for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture (see SmPC for the full indication) and it is given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen.

Further information about the evaluation of "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"'s benefits can be found in "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/summaries-opinion/teriparatide-sun.

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

Important risks of "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen", together with measures to minimise such risks and the proposed studies for learning more about "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"'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.

If important information that may affect the safe use of "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen"is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen" 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 "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen". 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	**None**
Important potential risks	**None**
Missing information	**None**

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product FORSTEO 20 micrograms/80 microliters Solution for injection in pre-filled pen, MAH: Eli Lilly Nederland B.V.

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 "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen".

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

There are no studies required for "Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen".