Summary of the Risk Management Plan

Summary of risk management plan for Forsteo (teriparatide)

This summary of the RMP for teriparatide should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of 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 Forsteo's risk management plan (RMP).

I. The medicine and what it is used for

Forsteo is authorised for treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated. Forsteo is also indicated for treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture (see Summary of Product Characteristics [SmPC] for the full indication). It contains teriparatide as the active substance and it is given by injection in a solution of 20 µg/80 µL.

Further information about the evaluation of Forsteo's benefits can be found in Forsteo's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage at http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000425/human_med_000798.jsp.

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

Important risks of Forsteo, together with measures to minimise such risks and the proposed studies for learning more about Forsteo's risks, are outlined as:

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 as 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

None.

II.B. Summary of important risks

Not applicable.

II.C. Post-authorisation development plan

II.C.1. Studies that are conditions of the marketing authorisation

There are no category 1 or 2 studies that are conditions of the marketing authorisation or specific obligation of Forsteo.

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

Not applicable.