Part VI: Summary of the risk management plan

Summary of risk management plan for Teriparatide (Teriparatide)

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

Teriparatide's proposed SmPC and its package leaflet provide essential information to healthcare professionals and subjects on how Teriparatide should be used.

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 which is part of the European Public Assessment Report (EPAR).

I. The medicine and what it is used for

Osteoporosis is a disease that makes bones fragile. Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and are more likely to break. Osteoporosis is possible in both men and women. In women, osteoporosis is more common after menopause, when the levels of the female hormone oestrogen become lower. Glucocorticoids are frequently prescribed in patients with a wide variety of chronic diseases, such as rheumatoid arthritis, polymyalgia rheumatic, inflammatory bowel disease, chronic obstructive pulmonary disease etc. Osteoporosis can occur in both men and women as a side effect of taking glucocorticoids.

Teriparatide is proposed for treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture; treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture. It contains Teriparatide as the active substance and it is given by subcutaneous injection in the thigh or abdomen.

Further information about the evaluation of Teriparatide's benefits can be found in Teriparatide'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/EPAR/kauliv

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

Important risks of Teriparatide, together with measures to minimise such risks for learning more about Teriparatide'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 subjects 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 subject (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 will be collected continuously and regularly analysed, including PSUR assessment 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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Teriparatide 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. 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):

Based on the PRAC Rapporteur Risk Management Plan (RMP) Assessment Report, there are no safety concerns in terms of important identified risks and potential risks. An assessment was done to evaluate whether immunogenicity should be considered as a missing information. The data available for clinical studies of teriparatide was reviewed in this regard. Based on the review of the clinical data, immunogenicity is not being considered as a missing information. Thus, there are no safety concerns for the product.

II.B Summary of important risks

Important identified risk
None
Important potential risk
None
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 authorisation or which is a specific obligation of Teriparatide.

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

There are no studies required for Teriparatide.