

Risk Management Plan Summary

Terrosa

Teriparatide

20 micrograms/80 microliters

Solution for injection

Document Version: 2.0

Document Date: 06.12.2021

Based on EU RMP Version: 2.2

Marketing Authorization Holder: Gedeon Richter (Schweiz) AG

Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Terrosa is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Terrosa in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

Gedeon Richter (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Terrosa.

Summary of risk management plan for Terrosa 20 micrograms/80 microliters solution for injection (teriparatide)

This is a summary of the risk management plan (RMP) for Terrosa 20 micrograms/80 microliters solution for injection. The RMP details important risks of Terrosa 20 micrograms/80 microliters solution for injection, how these risks can be minimised, and how more information will be obtained about Terrosa 20 micrograms/80 microliters solution for injection's risks and uncertainties (missing information).

Terrosa 20 micrograms/80 microliters solution for injection's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Terrosa 20 micrograms/80 microliters solution for injection should be used.

This summary of the RMP for Terrosa 20 micrograms/80 microliters solution for injection 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 Terrosa 20 micrograms/80 microliters solution for injection's RMP.

I. The medicine and what it is used for

Terrosa 20 micrograms/80 microliters solution for injection is authorised for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. Terrosa 20 micrograms/80 microliters solution for injection is also indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture. (See SmPC for the full indication). It contains teriparatide as the active substance and it is given by solution for injection.

Further information about the evaluation of Terrosa 20 micrograms/80 microliters solution for injection's benefits can be found in Terrosa 20 micrograms/80 microliters solution for injection's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage link to product's EPAR summary landing page on the EMA webpage.

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

Important risks of Terrosa 20 micrograms/80 microliters solution for injection, 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 — 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, including PSUR assessment - so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Terrosa 20 micrograms/80 microliters solution for injection 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 Terrosa 20 micrograms/80 microliters solution for injection. 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	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable.

The safety information in the product information is aligned to the reference 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 Terrosa.

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

There are no studies required for Terrosa.