RMP Summary

RMP Version 1.1 – 05-Oct-2021

Sondelbay®,

Injektionslösung in einem Fertiginjektor

ZL-Nr.: 68534

Teriparatid

Accord Healthcare AG
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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 minimise them.

The RMP summary of Sondelbay 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 Sondelbay in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Accord Healthcare AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Sondelbay.

Part VI: Summary of the risk management plan

Summary of risk management plan for Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen (teriparatide)

This is a summary of the risk management plan (RMP) for Sondelbay 20 micrograms/ 80 microliters solution for injection in pre-filled pen. The RMP details important risks of Sondelbay 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 Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen risks and uncertainties (missing information).

Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen's prescribing information (SmPC/ PIL) give essential information to healthcare professionals and patients on how Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen should be used.

Sondelbay 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 Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen's RMP.

I. The medicine and what it is used for

Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen is indicated in adults.

- 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 have been demonstrated.
- 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 subcutaneously.

Further information about the evaluation of Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen's benefits can be found in Sondelbay 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 <link to the EPAR summary landing page>.

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

Important risks of Sondelbay 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 Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen 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 and signal management activity, 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 Sondelbay 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 Sondelbay 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 Sondelbay 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);

Important identified risks	• None
Important potential risks	• None
Missing Information	• Potential for immunogenicity

II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal 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 authorization or specific obligation of Sondelbay 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 Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen.