Risk Management Plan Summary

Movymia

Teriparatide

20 micrograms/80 microliters

Solution for injection

Document Version: 1.0

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Based on EU RMP Version: 1.2

Marketing Authorization Holder: Spirig HealthCare 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 Movymia 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 Movymia in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

Spirig HealthCare AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Movymia.

Overview of disease epidemiology

Movymia is used for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and men who are at increased risk of fractures and in women and men who are at increased risk of fractures due to long-term treatment with glucocorticoids (a type of steroid). In the European Union osteoporosis affects about 6.6% of men and 22% of women over the age of 50. The highest number of women with osteoporosis is observed in the 75–79-year age group. However, for men the highest proportion of individuals with osteoporosis is found in the 60–64-year age group. 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. Long-term treatment with glucocorticoids may be responsible for up to 20% of all osteoporosis cases.

Summary of treatment benefits

As Movymia is a biosimilar medicine, a study in 54 healthy female subjects was conducted to show that Movymia produced similar levels of the active substance in the body as the reference medicine Forsteo®. The subjects received single doses of each medicine on 2 separate occasions.

Unknowns relating to treatment benefits

Duration of treatment should not exceed 24 months since the safety of teriparatide beyond this time has not been established. Safety and effectiveness in children and adolescents is not known. No data is available concerning patients with impaired liver function. There is little information about patients with severe kidney disease.

Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Abnormally high level of calcium in the blood (Hypercalcaemia)	Increases in the blood levels of calcium have been seen following injection with teriparatide but these tend to return to pre-treament levels within 16-24 hours. Abnormally high levels of calcium in the blood (Hypercalcaemia) is an uncommon side effect but severely abnormal levels are rare (may affect up to 1 in a 1000 people).	Patients who suffer from high calcium levels (pre-existing hypercalcaemia) must not use teriparatide.

Risk	What is known	Preventability
An abnormal decrease in blood pressure when a person stands up (Orthostatic hypotension)	An abnormal decrease in blood pressure when a person stands up (Orthostatic hypotension) may lead to dizziness or fainting. A few cases of an abnormal decrease in blood pressure on standing (Orthostatic hypotension) were seen in clinical trials. This happened within the first several doses and typically recovered within a few minutes to a few hours.	For the first doses, inject teriparatide where the patient can sit or lie down right away if they get dizzy. Patients should not drive or use machines until the symptoms get better.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Bone cancer [Osteosarcoma (potential risk from non-clinical finding)]	An increased incidence of bone cancer (Osteosarcoma) was seen in an experimental rat model prior to human clinical studies. However, this may be an effect specific to rats. Humans treated with teriparatide have been carefully assessed for this cancer but no cases of osteosarcoma that were related to teriparatide treatment have been seen. Patients with a previous history of bone cancer, or radiotherapy of the bones or Paget's disease of the bone should not use teriparatide. Until further clinical data becomes available patients must not take teriparatide for more than 24 months and treatment with teriparatide cannot be repeated after this period.
An accumulation of calcium in small blood vessels of the fat and skin tissues that causes painful skin ulcers and skin death in patients who do not have kidney problems (Non-uraemic calciphylaxis)	A few reports of a rare but serious condition involving a build-up of calcium in the blood vessels of the skin and fat in patients who did not have kidney problems (Non-uraemic calciphylaxis) have been reported in patients receiving treatment with teriparatide. These cases are being investigated further to establish whether teriparatide or other potential factors were responsible for causing this condition in these patients.

Missing information

Risk	What is known
Immunogenicity	Based on the information available immune response might develop in very rare cases in patients receiving teriparatide treatment. On the basis of the information generated for the originator's product Forsteo® anti-teriparatide antibodies might be detectable at least 12 months after the start of treatment, persist without any consequence for either efficacy or safety and tend to disappear following the cessation of teriparatide treatment. There is no evidence that antibody formation has an effect on the safety and efficacy of the reference product, consequently it is not expected to have any impact in the case of Movymia either.

Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, information on the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the Package Leaflet (PL). The measures outlined in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

Post-authorisation pharmacovigilance development plan

Study/activity type, title and category (1-3)	**Objectives**	**Safety concerns addressed**	**Status (planned, started)**	**Date for submission of interim or final reports (planned or actual)**
RGB-10 Phase III Clinical study RGB1023O31: A comparative study to evaluate the similarity of RGB-10 to Forteo® in patients with osteoporosis at high risk of fracture Category 3.	Providing immunogenicity data during treatment with RGB-10. Furthermore assessing the clinical relevance (efficacy or safety consequences) of anti-teriparatide antibody formation.	Missing Information of Immunogenicity	Started in Q1 2016	Planned: December 2018

Studies which are condition of the marketing authorization

Not applicable.

Summary of changes to the risk management plan over time

Not applicable.