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Swiss Summary of the Risk Management Plan (RMP) for Prolia® (denosumab)

EU RMP: Version 33.1, 05 November 2025

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

The medicine and what it is used for

Prolia is authorized for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures, and treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture (see SmPC for the full indication). It contains denosumab as the active substance and it is given by subcutaneous injection.

Further information about the evaluation of Prolia's benefits can be found in Prolia's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage: <https://www.ema.europa.eu/medicines/human/EPAR/prolia>.

Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Prolia®, together with measures to minimize such risks and the proposed studies for learning more about Prolia's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 public (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In the case of Prolia, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (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 Prolia is not yet available, it is listed under 'missing information' below.

List of Important Risks and Missing Information

Important risks of Prolia are risks that need special risk management activities to further investigate or minimize 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 Prolia. 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 (eg, on the long-term use of the medicine).

Summary of safety concerns

List of important risks and missing information

Important identified risk	- Hypocalcemia - Osteonecrosis of the jaw
Important potential risk	None
Missing information	None

Summary of Important Risks

Important identified risk: Hypocalcemia	
Evidence for linking the risk to the medicine	This risk was identified in the phase 3, randomized, double-blind, placebo- or active-controlled studies.
Risk factors and risk groups	Risk factors include severe renal impairment and hyperphosphatemia. Other risks factors may include a history of hypoparathyroidism, parathyroid hormone resistance, vitamin D deficiency or resistance, thyroid surgery, parathyroid surgery, malabsorption syndromes, excision of small intestine, severe renal impairment (creatinine clearance < 30 mL/min), dialysis, and some medications (Finkelstein, 2001).
Risk minimization measures	Routine risk minimization measures: - SmPC Section 4.4, where recommendation regarding correction and monitoring of calcium levels is provided - SmPC Section 4.2, 4.3, and 4.8 - PL Section 2 and 4 Additional risk minimization measures: - None

Important identified risk: Osteonecrosis of the jaw	
Evidence for linking the risk to the medicine	This risk was identified in open-label long-term extensions to phase 3, randomized, double-blind, placebo-controlled studies.
Risk factors and risk groups	Risk factors include duration of exposure to denosumab, prior bisphosphonate use (particularly for extended periods of time), older age, periodontal disease, dentoalveolar surgery, trauma from poorly fitting dentures, malignancy, chemotherapy, corticosteroids, smoking, systemic or regional infection, immune-compromised state predisposing to increased risk of infection, hypercoagulable state secondary to underlying malignancy, and vascular insufficiency due to thrombosis (Mehrotra and Ruggiero, 2006).
Risk minimization measures	Routine risk minimization measures: • SmPC Section 4.4, where oral hygiene and dental management guidance is provided • SmPC Section 4.8 • PL Section 2 and 4 Additional risk minimization measures: • Patient reminder card

Post-authorization development plan

Studies which are a condition of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Prolia.

Other studies in Postauthorization Development Plan

There are no studies required for Prolia.

This summary was last updated in September 2026.

References

Finkelstein JS. The parathyroid glands, hypercalcemia, and hypocalcemia.
In: Carpenter CCJ, Griggs RC, Loscalzo J, eds. Cecil Essentials of Medicine, 5th ed.
Philadelphia, PA: WB Saunders Company; 2001;639-648.

Mehrotra B, Ruggiero S. Bisphosphonate complications including osteonecrosis of the jaw. Hematology. 2006;356-360.