



PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

This is a summary of the Risk Management Plan (RMP) for the following products:

- TREDIMIN 10.000 U.I./ml gocce orali, soluzione
- TREDIMIN 25.000 U.I./2,5 ml soluzione orale
- TREDIMIN 50.000 U.I./2,5 ml soluzione orale
- TREDIMIN 10.000 U.I. capsule molli
- TREDIMIN 25.000 U.I. capsule molli
- TREDIMIN 50.000 U.I. capsule molli

The RMP details important risks of TREDIMIN, how these risks can be minimized, and how more information about cholecalciferol's risks and as well as the uncertainties surrounding the information available (missing information) will be obtained.

TREDIMIN's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients about how TREDIMIN should be used.

New important concerns or changes to the current ones will be included in updates to TREDIMIN's RMP.

I. The medicine and what it is used for

TREDIMIN is authorised for prevention and treatment of vitamin D deficiency (see SmPC for the full indication). It contains cholecalciferol as the active substance and it is administered orally.



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

Important risks of TREDIMIN along with measures to minimize those risks and any proposed studies for learning more about the risks of TREDIMIN use, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on proper use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicinal product's packaging;
- The authorized pack size — the amount of medicine in a package is chosen to ensure that the medicine is used properly;
- The medicinal product's legal status — the way a medicinal product is provided to the patient (e.g. with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

Information about adverse reactions is collected continuously and analysed regularly, so that immediate action can be taken if necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of TREDIMIN are risks that require special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken.

Important risks may be considered identified or potential risks.



Identified risks are concerns for which there is sufficient evidence of a link to the use of TREDIMIN.

Potential risks are concerns for which an association with the use of this medicinal product is possible based on available data, but that association has not yet been established and needs further evaluation.

Missing information refers to information about the safety of the medicinal product that is currently missing and needs to be collected (e.g., about long-term use of the drug).

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not Applicable.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies that are conditions of the marketing authorization or specific obligation of TREDIMIN.

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

There are no studies required for TREDIMIN.