

## RMP version 2.1

### Part VI: Summary of the risk management plan

#### Summary of risk management plan for Oleo-De3 oral drops, solution (Cholecalciferol)

This is a summary of the risk management plan (RMP) for Oleo-De3 oral drops, solution. The RMP details important risks of Oleo-De3 oral drops, solution how these risks can be minimised, and how more information will be obtained about Oleo-De3 oral drops, solution.

Oleo-De3 oral drops, solution SmPC and its PL give essential information to healthcare professionals and patients on how Oleo-De3 oral drops, solution should be used.

Important new concerns or changes to the current ones will be included in updates of Oleo-De3 oral drops, solution's RMP.

#### I. The medicine and what it is used for

Oleo-De3 oral drops, solution contains the active substance cholecalciferol (vitamin D3).

Oleo-De3 oral drops, solution is approved in the following indications:

- Prevention and treatment of vitamin D deficiency
- Treatment of rickets
- As an adjunct to a specific therapy for osteoporosis in patients at risk of vitamin D deficiency

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

Important risks of Oleo-De3 oral drops, solution, together with measures to minimise such risks and the proposed studies for learning more about Oleo-De3 oral drops, solution 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 PL 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, 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 Oleo-De3 oral drops, solution 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 Oleo-De3 oral drops, solution. 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 and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

## 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 authorisation or specific obligation of Oleo-De3 oral drops, solution.

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

There are no on-going or closed studies for Oleo-De3 oral drops, solution.