# Summary of the EU Risk Management Plan (RMP)

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|---|---|
| Name of the medicinal product: | Lundeos<br>(Vitamin D3, 1000 IU and 20000 IU Capsules, Soft), |
| Active substance: | Cholecalciferol |
| Version number of the current RMP: | 1.0 |
| Name of the marketing authorisation holder: | Future Health Pharma GmbH |
| Data lock point for the RMP: | 04 January 2020 |
| Date of RMP: | 19. February 2020 |

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 “Lundeos” (Vitamin D3, 1000 IU and 20000 IU Capsules, Soft), 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 “Lundeos” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. “Future Health Pharma GmbH” is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Lundeos”.

**PART VI- Summary of the risk management plan**

# Summary of risk management plan for Vitamin D3 (Cholecalciferol)

This is a summary of the risk management plan (RMP) for Vitamin D3. The RMP details important risks of Vitamin D3 and how more information will be obtained about Vitamin D3's risks and uncertainties (missing information).

Vitamin D3's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Vitamin D3 should be used.

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

Vitamin D3 is authorised for the treatment (20000 IU and 1000 IU) and prevention (1000 IU) of Vitamin D deficiency (see SmPC for the full indication). It contains Cholecalciferol as the active substance and it is given by oral route administration.

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

Important risks of Vitamin D3, together with measures to minimise such risks and the proposed studies for learning more about Vitamin D3's 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 medicines 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 analyzed, 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 Vitamin D 20 000 IU and 1000 IU are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely

taken. 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 Vitamin D 20 000 IU and 1000 IU. 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

Not applicable.

## 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 Vitamin D3.

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

There are no studies required for Vitamin D3.