# Part VI: Summary of the risk management plan

Summary of risk management plan for Decurol 5.600 I.U/12.500 I.U./25.000 I.U capsule hard (Cholecalciferol).

This is a summary of the risk management plan (RMP) for Decurol 5.600 I.U/12.500 I.U./25.000 I.U capsule hard. The RMP details important risks of Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and and Decurol 25.000 I.U., capsule hard, and how more information will be obtained about Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard 's risks and uncertainties (missing information).

Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard should be used.

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

Prevention and treatment of vitamin D deficiency in adults and adolescents..

In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency..

Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard contain CHOLECALCIFEROL as active substance and they are given by oral route.

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

Important risks of Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard, together with measures to minimise such risks and the proposed studies for learning more about Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard '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 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 Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard 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 Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard. 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 Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard.

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

There are no studies required for Decurol 5.600 I.U., capsule hard, Decurol 12.500 I.U., capsule hard and Decurol 25.000 I.U., capsule hard.