Summary of the risk management plan for Hidroferol semanal (Calcifediol)

This is a RMP for Hidroferol semanal. The RMP details important risks of Hidroferol semanal, how these risks can be minimised, and how more information will be obtained about Hidroferol semanal' risks and uncertainties (missing information).

Hidroferol semanal' SmPC and its package leaflet give essential information to healthcare professionals and patients on how Hidroferol semanal should be used.

Important new concerns or changes to the current ones will be included in updates of Hidroferol semanal' RMP.

I. The medicine and what it is used for

Hidroferol semanal is indicated for treatment of vitamin D deficiency (i.e. 25(OH)D levels <25 nmol/L) in adults and as adjuvant for the specific treatment of osteoporosis in patients with vitamin D deficiency or at risk of vitamin D deficiency. Furthermore, some formulations have also the following indication prevention of vitamin D deficiency in adults with identified risks such as in patients with malabsorption syndrome, chronic kidney disease mineral and bone disorder or other identified risks (there are several doses for Hidroferol semanal, thus see SmPC for the full indication). It contains calcifediol as the active substance and it is given by oral route.

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

Important risks of Hidroferol semanal, together with measures to minimise such risks and the proposed studies for learning more about Hidroferol semanal' 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: in order to minimise medication errors, section 4.2 of the SmPC states that Hidroferol semanal *should not be administered with a daily frequency*;
- Important advice on the medicine's packaging: in order to minimise medication errors, a warning stating that Hidroferol semanal *is not for daily use* is included 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.
- Product name includes "semanal"* reinforcing the message that Hidroferol semanal is for a weekly frequency use.

  **Semanal means weekly in Spanish*

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, 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 Hidroferol semanal 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 Hidroferol semanal. 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 risk

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 Hidroferol semanal.

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

There are no studies required for Hidroferol semanal.