

# Summary of risk management plan for HERCAL

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

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

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

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

HERCAL is authorised for

Adults:

Treatment of vitamin D deficiency in cases where the initial administration of high doses is necessary or where it is preferable to have a delayed administration, as in the following situations:

- as an adjunct in the treatment of osteoporosis
- in patients with malabsorption syndrome
- renal osteodystrophy
- bone diseases induced by corticosteroid treatment

It contains calcifediol as the active substance and it is given by mouth.

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

Important risks of HERCAL, together with measures to minimise such risks and the proposed studies for learning more about HERCAL'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.

If important information that may affect the safe use of HERCAL is not yet available, it is listed under 'missing information' below.

## **II.A List of important risks and missing information**

Important risks of HERCAL 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 HERCAL. 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);

<b>List of important risks and missing information</b>	
Important identified risks	Hypercalcaemia Cardiac failure Drug interaction (thiazide diuretics, cardiac glycosides) Use in renal failure Calcic lithiasis Hypersensitivity Overdose
Important potential risks	Use during lactation Use during pregnancy
Missing information	None

## **II.B Summary of important risks**

<b>Important identified risk: Hypercalcemia</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Hypercalcemia, primary hyperparathyroidism
Risk minimisation measures	Routine risk minimisation measures  No risk minimisation measures

<b>Important identified risk: Cardiac failure</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Cardiac failure, concomitant treatment with thiazide diuretics and cardiac glycosides.
Risk minimisation measures	Routine risk minimisation measures

	No risk minimisation measures
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<b>Important identified risk: Drug interaction (with thiazide diuretics, cardiac glycosides)</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Cardiac failure, patients treated concomitantly with thiazide diuretics or cardiac glycosides
Risk minimisation measures	Routine risk minimisation measures
	No risk minimisation measures

<b>Important identified risk: Use in renal failure</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Chronic Kidney Disease
Risk minimisation measures	Routine risk minimisation measures
	No risk minimisation measures

<b>Important identified risk: Calcic lithiasis</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Calcium lithiasis, hypercalciuria.
Risk minimisation measures	Routine risk minimisation measures
	No risk minimisation measures

<b>Important identified risk: Hypersensitivity</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Patients with known hypersensitivity to the active substance or excipients
Risk minimisation measures	Routine risk minimisation measures
	No risk minimisation measures

<b>Important identified risk: Overdose</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Administration of vitamin D in high doses or for long periods of time.
Risk minimisation measures	Routine risk minimisation measures No risk minimisation measures

<b>Important potential risk: Use during lactation</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Lactation
Risk minimisation measures	Routine risk minimisation measures No risk minimisation measures

<b>Important potential risk: Use during pregnancy</b>	
Evidence for linking the risk to the medicine	This safety information proposed is aligned to the medicinal product NEODIDRO 0.266 mg soft capsules
Risk factors and risk groups	Pregnancy
Risk minimisation measures	Routine risk minimisation measures No risk minimisation measures

## ***II.C Post-authorisation development plan***

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

#### **Study short name**

There are no studies which are conditions of the marketing authorisation or specific obligation of HERCAL.

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

There are no studies required for HERCAL.