Part VI:
Summary of the risk management plan for Lanthanum Orifarm

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

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

I. The medicine and what it is used for

Lanthanum Orifarm is authorised for hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

It contains lanthanum as the active substance and it is administered as chewable tablets.

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

Important risks of Lanthanum Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Lanthanum Orifarm'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 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 Lanthanum Orifarm 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 Lanthanum Orifarm. 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	• Gastrointestinal obstruction, Ileus, Subileus, Gastrointestinal perforation • Lanthanum deposition in the gastrointestinal tract
Important potential risks	• Lanthanum deposition (e.g. bone, liver) • Systemic allergic reactions • Medication error associated with incompletely chewed/unchewed tablet
Missing information	• Effects of lanthanum deposition on long term use

II.B Summary of important risks

Safety Concern	**Routine risk minimisation activities**	**Pharmacovigilance activities**
Important identified risks		
Gastrointestinal obstruction, Ileus, Subileus, Gastrointestinal perforation	Routine risk communication: • SmPC: section 4.4, section 4.8 • PIL: section 2, section 4	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.
Lanthanum deposition in the gastrointestinal tract	Routine risk communication: • SmPC: section 4.4, 4.8 and 5.3 • PIL: section 2, section 4	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.
Important potential risks		
Lanthanum deposition (e.g. bone, liver)	Routine risk communication: • SmPC: section 4.4, section 4.8, section 5.3 • PIL: section 2, section 4	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.

Systemic allergic reactions	Routine risk communication: • SmPC: section 4.3, section 4.8 • PIL: section 4	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.
Medication error associated with incompletely chewed/unchewed tablet	Routine risk communication: • SmPC: section 4.2, section 4.4 • PIL: section 2, section 3	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.
Missing information		
Effects of lanthanum deposition on long term use	Routine risk communication: SmPC: section 4.4	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: *None*. Additional pharmacovigilance activities: *None*.

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 Lanthanum Orifarm.

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

There are no studies required for Lanthanum Orifarm.