Summary of risk management plan for Velphoro (sucroferric oxyhydroxide)

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

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

This summary of the RMP for Velphoro should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The Medicine and What it is Used for

Velphoro is authorised for the control of blood phosphate levels in adult chronic kidney disease patients who are undergoing haemodialysis or peritoneal dialysis (see SmPC for the full indication). It contains sucroferric oxyhydroxide (mixture of polynuclear iron(III)-oxyhydroxide, sucrose and starches) as the active substance and it is given orally.

Further information about the evaluation of Velphoro's benefits can be found in Velphoro's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/velphoro.

II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Velphoro, together with measures to minimise such risks and the proposed studies for learning more about Velphoro 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 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 Periodic Safety Update Report assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

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

II.A. List of Important Risks and Missing Information

Important risks of Velphoro 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 Velphoro. 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 Risk	None
Important Potential Risk	None
Missing Information	None

II.B. Summary of Important Risks

Important Identified Risk: None	
Evidence for linking the risk to the medicine	N/A
Risk factors and risk groups	N/A
Risk minimisation measures	N/A
Important Potential Risk: None	
Evidence for linking the risk to the medicine	N/A
Risk factors and risk groups	N/A
Risk minimisation measures	N/A

Note: N/A=Not applicable.

Missing Information: None	
Risk minimisation measures	N/A

Note: N/A=Not applicable.

II.C. Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are currently no post-authorisation safety or efficacy studies for Velphoro that are specific obligations and/or conditions of the marketing authorisation.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies in post-authorisation development plan.