PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Extraneal Solution for peritoneal dialysis (icodextrin 7.5%)

This is a summary of the Risk Management Plan (RMP) for Extraneal Solution for peritoneal dialysis (hereafter Extraneal). The RMP provides details on the risks of Extraneal, and how these risks can be minimized.

The Summary of Product Characteristics (SmPC) and Package Leaflet (PL) for Extraneal provide essential information to healthcare professionals and patients on how Extraneal should be used.

New safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Extraneal is recommended as a once daily replacement for a single glucose exchange as part of a CAPD or APD regimen for the treatment of chronic renal failure, particularly for patients who have lost ultrafiltration on glucose solutions, because it can extend time on CAPD therapy in such patients. It contains icodextrin 7.5% in an electrolyte solution as the active substance, and it is given by intraperitoneal administration.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

The important risks of Extraneal, together with measures to minimize such risks, are outlined below. Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size – the amount of medicine in a pack is chosen so as 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).

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

In the case of Extraneal, these measures are supplemented with *additional risk minimization measures* mentioned under the "summary of risks and missing information" section, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (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 medicinal products are risks that need special risk management activities to further investigate or minimize 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 medicinal products. Potential risks are concerns for which an association with the use of the medicinal product is possible based on available data, but this association has not been established yet and needs to be further monitored. Missing information refers to information on the safety of the medicinal product that is currently missing and further information may need to be collected (e.g., on the long-term use of the medicine).

The important risk for Extraneal is listed in the table below.

List of important risks and missing information	
Important identified risks	Falsely elevated glucose readings due to use of GDH-PQQ-, GDO-, or some GDH-FAD-based glucometers and test strips
Important potential risks	None
Missing information	None

II.B Summary of important risks and missing information

Important identified risk: Falsely elevated glucose readings due to use of GDH-PQQ-, GDO-, or some GDH-FAD-based glucometers and test strips	
Evidence for linking the risk to the medicine	Post-marketing reports and medical literature. Reports of unrecognized hypoglycemia, which have led to loss of consciousness, coma, permanent neurological damage, and death have been received in the post-marketing setting.

Risk factors and risk groups	All patients on Extraneal therapy who utilize non-glucose-specific glucometers or test strips or are treated at a facility using non-glucose-specific glucometers for blood glucose measurement are at risk.
Risk minimization measures	**Routine risk minimization measures:** Discussed in sections 4.4 and 4.5 of the SmPC. Listed in section 4.8 of the SmPC. Discussed in section 2 of the PL. **Additional risk minimization measures:** • Maintain global glucose monitor compatibility list as reference for HCPs and patients. • Distribution of the following risk minimization tools upon commercialization of Extraneal and maintain a country website: - Wallet card, - Hospital admission kit consisting of a letter and chart sticker providing actionable communication to HCPs, - Website supporting electronic safety messaging.

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligations of Extraneal.

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

There are no studies required for Extraneal.