

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Physioneal

This is a summary of the risk management plan (RMP) for Physioneal 35 and 40 in Viaflex and Clear-Flex; hereafter referred to Physioneal unless specified. The RMP provides details on the updates to the important risks of Physioneal.

The summary of product characteristics (SmPC) and package leaflet (PL) for Physioneal provide essential information to healthcare professionals and patients on how Physioneal should be used.

I. The medicine and what it is used for

Physioneal is authorized whenever peritoneal dialysis is employed, including, acute and chronic renal failure, severe water retention, severe electrolyte imbalance, drug intoxication with dialyzable substances, and when a more adequate therapeutic alternative is not available. Physioneal is bicarbonate/lactate based peritoneal dialysis solution, with a physiological pH, particularly indicated in patients in whom solutions based on a lactate buffer only, with a low pH, cause abdominal inflow pain or discomfort; refer to the SmPC for complete indication wording. Physioneal is intended for intraperitoneal administration only and contains the following active substances:

Physioneal 35 and 40

Chamber A: Glucose monohydrate, calcium chloride dihydrate, and magnesium chloride hexahydrate.

Chamber B: Sodium chloride, sodium bicarbonate, and sodium lactate solution.

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

There are no important risks included in the RMP for Physioneal; however, measures to minimize the risks for any medicinal products may 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 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) can help to minimize its risks.

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

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

The important risks of Physioneal 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 the medicinal product. Potential risks are concerns for which an association with the use of the 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). There are no safety concerns (important risks or missing information) for Physioneal.

II.B Summary of important risks and missing information

There are no safety concerns included in this RMP for Physioneal. All risks associated with the use of Physioneal are considered fully characterized and appropriately managed with routine risk minimization measures in the product information which are fully integrated into standard clinical practice.

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 Physioneal.

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

There are no studies required for Physioneal.