

Initial REMS Approval 03/2011
Most Recent Modification 10/2016

NDA 021321

EXTRANEAL (icodextrin) Peritoneal Dialysis Solution

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

To mitigate the risk of morbidity and mortality associated with the use of non-specific glucose monitors and test strips in patients using EXTRANEAL by:

- Informing the dialysis clinic staff managing the patient's treatment (such as peritoneal dialysis nurses) about the drug-device interaction and the potential for falsely elevated blood glucose readings in patients using EXTRANEAL.
- Informing patients of the drug-device interaction and the need to alert health care providers of this interaction whenever they receive treatment outside of a dialysis clinic.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each EXTRANEAL prescription in accordance with 21 CFR 208.24.

B. Elements to Assure Safe Use

1. EXTRANEAL will only be dispensed to patients with documentation of safe-use conditions

- a. Baxter will ensure that EXTRANEAL is only dispensed to patients if there is documentation that the dialysis clinic staff managing the patient's treatment has completed the training on drug-device interactions involving EXTRANEAL. The "Dialysis Clinic Training" on drug-device interactions consists of the following:
 - i. Why EXTRANEAL patients have elevated blood levels of maltose;
 - ii. How maltose interferes with non-specific glucose monitoring systems;
 - iii. How maltose interference with non-specific glucose monitoring systems may result in falsely elevated blood glucose readings;
 - iv. What are the consequences of falsely elevated blood glucose readings;
 - v. The risk of maltose interference with non-specific glucose monitoring systems for up to 14 days following cessation of EXTRANEAL therapy;
 - vi. How to confirm that patients are using glucose-specific monitors and test strips;
 - vii. How to use the Baxter tools that are available to assist with training of dialysis clinic staff, and to assist the dialysis clinic staff with training EXTRANEAL patients;
 - viii. The importance of educating patients to alert health care providers of the drug-device interaction whenever they are admitted to the hospital or in other medical care settings;
 - ix. Information on the EXTRANEAL Patient Kit - how it should be used, what it contains, and how patients will receive it;
 - x. Contact information for glucose monitor manufacturers; and
 - xi. Contact information for MedAlert.

 - b. Dialysis clinic staff are responsible for training patients at the time EXTRANEAL is added to their prescriptions. The patient training includes:
 - i. The importance of verifying that home glucose monitors and test strips are glucose-specific;
 - ii. Why only glucose-specific monitors and test strips should be used;
 - iii. The potential consequences that can result if glucose-specific monitors and test strips are not used;
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- iv. The need to alert health care providers of the potential for glucose monitor interference when admitted to the hospital or in other medical care settings;
 - v. The importance of informing caregivers of the potential for falsely elevated glucose readings and the need to communicate this information in an emergency situation on the patient's behalf;
 - vi. The risk of glucose monitor interference for up to 14 days after stopping use of EXTRANEAL;
 - vii. A review of the EXTRANEAL Patient Kit, which includes the following:
 - 1) Patient Letter;
 - 2) EXTRANEAL Patient Training Tool;
 - 3) EXTRANEAL Wallet/Key Card;
 - 4) EXTRANEAL Wearable Item (e.g., a bracelet and/or pendant);
 - 5) Stickers and a magnetic hang tag for patient charts and prominent display in the hospital setting;
 - 6) Letters to hospital staff, including:
 - a. Physicians
 - b. Nurses
 - c. Pharmacists
 - d. Laboratory Services
 - e. Admissions Personnel
 - 7) EXTRANEAL Prescribing Information; and,
 - 8) EXTRANEAL Medication Guide.
 - viii. Informing patients that the EXTRANEAL Patient Kit will be delivered directly to the patient's home in parallel with the first delivery of their EXTRANEAL prescription.
- c. If a dialysis clinic's staff have not managed the treatment of a patient using EXTRANEAL within six months of having completed training, Baxter will ensure that the staff are re-trained before EXTRANEAL is dispensed.
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The following materials are part of the REMS and are appended:

- EXTRANEAL PD Nurse Training Tool (Attachment 1)
- EXTRANEAL Patient Training Tool (Attachment 2)
- EXTRANEAL Patient Kit (Attachment 3)

C. Implementation System

1. Baxter will maintain a database of all dialysis clinics whose staff have been trained and the date training was completed.
2. Baxter will maintain a database of all patients who are dispensed EXTRANEAL.
3. Baxter will maintain a database of all patients who have received the EXTRANEAL Patient Kit and the date the Patient Kit was received by the patient.
4. Baxter will verify that all patients dispensed EXTRANEAL received a Patient Kit, by tracking the shipment of the Patient Kit and obtaining delivery confirmation.
5. Baxter will update the U.S. country-specific glucose monitor list found at www.glucosafety.com every six months.
6. Based on evaluation of the implementation of elements to assure safe use provided for under Sections B1 above, and in the manner described in the REMS supporting document, Baxter will take reasonable steps to improve implementation of these elements to meet the goals of the REMS.

D. Timetable for Submission of Assessments

Baxter will submit REMS Assessments to FDA February 28, 2012 and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Baxter will submit each assessment so that it will be received by FDA on or before the due date.
