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NDA 21-321

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

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- 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 MedicAlert.
- 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;
 - 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;

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- 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.

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 monitor compliance with the EXTRANEAL program to help ensure that EXTRANEAL is dispensed to patients who have received training by their dialysis clinic, by conducting surveys of patients.
6. Baxter will update the U.S. country-specific glucose monitor list found at www.glucosafety.com every six months.
7. 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.

Attachment 1

EXTRANEAL PD Nurse Training Tool

(8 pages)



Using **Extraneal** (icodextrin) Peritoneal Dialysis Solution

PD NURSE TRAINING TOOL

Baxter

Important Risk Information for HCPs treating Patients Using Extraneal (icodextrin) Peritoneal Dialysis Solution

The following risk information about **Extraneal** PD Solution pertains to **ALL PATIENTS USING Extraneal** PD Solution, **whether or not they have diabetes.**

What are the potential risks with Extraneal PD Solution use and glucose monitors and test strips?

Use of **Extraneal** PD Solution results in elevated blood glucose levels of maltose, a metabolite of icodextrin. Maltose interferes with glucose monitors that utilize certain enzymes on their test strips resulting in falsely elevated blood glucose monitor readings. Specifically:

- glucose dehydrogenase pyroloquinolinequinone (GDH-PQQ)
- glucose-dye-oxidoreductase (GDO)
- and in some cases, glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)

The interference may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia.

Glucose monitors that use GDH-PQQ, GDO, and in some cases GDH-FAD **MUST NOT** be used for patients using **Extraneal** PD Solution.

What concerns might the patient have if someone checks their blood glucose levels?

Extraneal PD Solution can cause falsely elevated blood glucose readings, for up to **14 days** after its last use, regardless of the patient's diabetic status.

Extraneal PD Solution or its by-products, such as maltose, can cause some types of glucose monitors and/or test strips, including devices used at hospitals, clinics, and by emergency medical personnel, to give a **falsely elevated blood glucose reading.**

Use laboratory-based methods or verify the point-of-care glucometer and test strips are compatible for use in patients using **Extraneal** PD Solution.

What are the risks associated with having a “falsely elevated blood glucose reading?”

■ **Situation A:** A falsely elevated blood glucose reading **may lead to the erroneous diagnosis of hyperglycemia.**

POTENTIAL RISK—A falsely elevated blood glucose reading could cause you or another clinician to administer insulin to the PD patient that is not needed.

■ **Situation B:** A falsely elevated blood glucose reading **may mask true hypoglycemia.**

POTENTIAL RISK—A falsely elevated blood glucose reading could cause you or another clinician to assume that a PD patient's blood glucose level is normal when their true (hospital central lab) blood glucose level may be dangerously low — causing the patient to subsequently enter a hypoglycemic state if the appropriate steps are not taken to bring their blood glucose level back into normal range.

■ **BOTH** of these situations can result in unrecognized hypoglycemia and may lead to the following life-threatening events or reactions:

- Loss of Consciousness
- Coma
- Permanent Neurological Problems
- Death

Recommendations for Patient Training Regarding Glucose Monitors and Test Strips

- ✓ Train ALL patients and caregivers on the importance of using only glucose-specific monitors and test strips and about the potential life-threatening consequences if these guidelines are not followed. Instruct them to ensure that any emergency contacts also be made aware of this information
- ✓ Reinforce the need for ALL patients to alert health care providers outside the dialysis unit (e.g., emergency room, hospital, outpatient clinic, physician offices) of the potential risk of incorrect blood glucose monitor readings
- ✓ Use the **Extraneal** (icodextrin) PD Solution Patient Training Tool and **Extraneal** PD Solution Patient Medication Guide to educate ALL patients about glucose monitor and test strip interference
- ✓ Assist patients in completing the information on the Wallet Card included in the **Extraneal** PD Solution Patient Training Tool
- ✓ Your PD unit has received a Demonstration Kit, which contains a sample of all the items included in the **Extraneal** PD Solution Patient Kit. Prior to initiating therapy with **Extraneal** PD Solution, review the contents of the kit with patients, and inform them that an **Extraneal** PD Solution patient kit will be delivered to their home shortly

Additional considerations when training diabetic patients using **Extraneal** PD Solution:

- ✓ Verify the type of glucose monitor and test strips used by the patient; call or instruct the patient to call the manufacturers to verify that the monitor and/or test strips measure only glucose. Monitors and test strips that are subject to maltose interference must not be used



To assist in patient training, Baxter has developed an **Extraneal** PD Solution Patient Training Tool that contains important risk information about **Extraneal** PD Solution specifically intended for patients.

Baxter recommends that each patient be given a copy of the **Extraneal** PD Solution Patient Training Tool and that all information in the tool be discussed with the patient in detail.

If you need additional training materials — including **Extraneal** PD Solution Demonstration Kits (or any of its components), Patient Training Tools, and Nurse Training Tools — free of charge from your Baxter Clinical Educator or your Account Executive at **1-888-736-2543**.

If any of your patients need a replacement of any of the components in the **Extraneal** PD Solution Patient Kit — such as a necklace and/or bracelet — please have them contact HomeCare Services at **1-800-284-4060**

Protect **All** Patients.

- 1 Ensure all blood glucose measurements for patients using **Extraneal** (icodextrin) PD Solution are done with a method that does not cause maltose interference with test results
- 2 DO NOT use glucose monitoring systems that utilize the following enzymes on their test strips:
 - Glucose Dehydrogenase Pyrroloquinolinequinone (GDH-PQQ),
 - Glucose-Dye-Oxidoreductase (GDO), and
 - Glucose Dehydrogenase Flavin-Adenine Dinucleotide (GDH-FAD) [in some cases]
- 3 Remind patients to take their Patient Kit with them to ALL medical appointments — including visits to the emergency room or hospital
- 4 If hypoglycemia is suspected do not delay treatment since severe hypoglycemia may lead to life-threatening consequences including loss of consciousness, coma, permanent neurological problems and death. Confirm blood glucose readings using a laboratory-based method whenever available

If you are unsure of the method used by a specific glucose monitoring system, please contact the manufacturer to determine if the test strips are glucose-specific.

Glucose Monitor Manufacturers

The following list provides the names and contact information for manufacturers of today's most commonly used glucose monitors and test strips. It is included for reference only; you need to contact the manufacturer to ensure that the monitor and test strips use a method that does not cause maltose interference with test results. **This list does not indicate that Baxter is recommending these products. For further information, visit www.glucosafety.com.**

Manufacturer	Contact Information	
Abbott Diabetes Care	888-522-5226	www.abbottdiabetescare.com
AgaMatrix, Inc.	866-906-4197	www.agamatrix.com
Arkray	800-818-8877, Option #5	www.arkrayusa.com
Bayer Healthcare	800-348-8100	www.bayerdiabetes.com
Lifescan, Inc (Division of Johnson & Johnson)	800-227-8862	www.lifescan.com
NovaBiomedical	800-458-5813, 781-894-0800	www.novabiomedical.com
Roche Diagnostics	800-858-8072	www.roche-diagnostics.com www.accu-chek.com

Medic Alert

If your patients are MedicAlert members, or members of another medical alert service, be sure to encourage them to update their medical information. MedicAlert can be reached at **1-888-633-4298** or at www.medicalert.org

If your patients are not members of a medical alert service, encourage them to wear the **Extraneal** PD Solution necklace or bracelet provided by Baxter in the **Extraneal** PD Solution Patient Kit — this could help to save their lives

Extraneal (icodextrin) PD Solution Indications and Important Risk Information

Indications

Extraneal (icodextrin) Peritoneal Dialysis (PD) solution is indicated for a single daily exchange for the long (8 to 16 hour) dwell during Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) for the management of End-Stage Renal Disease (ESRD). **Extraneal** solution is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high-average or greater transport characteristics, as defined using the Peritoneal Equilibration Test (PET).

Important Risk Information:

WARNING: UNRECOGNIZED HYPOGLYCEMIA RESULTING FROM DRUG-DEVICE INTERACTION

- Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of EXTRANEAL (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.
- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosafety.com.
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

- **Extraneal** (icodextrin) is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with pre-existing severe lactic acidosis.
- **Extraneal** PD solution is intended for intraperitoneal administration only. Not for intravenous injection. Aseptic technique should be used throughout the peritoneal dialysis procedure.
- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using **Extraneal** PD solution.

- Serious hypersensitivity reactions to **Extraneal** PD solution have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Institute appropriate therapeutic countermeasures as clinically indicated.
- Effective use of **Extraneal** PD solution may be compromised in patients with abdominal conditions predisposing them to complications of peritoneal dialysis, including infection.
- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with **Extraneal** PD solution. Monitor blood glucose and adjust insulin, if needed.
- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.
- In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients and more common in **Extraneal** PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse event for **Extraneal** PD solution patients was skin rash.
- Please see Package Insert for full Prescribing Information.





www.baxter.com

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Attachment 2

EXTRANEAL Patient Training Tool

(12 pages)



Using **Extraneal** (icodextrin) Peritoneal Dialysis Solution

PATIENT TRAINING TOOL

Baxter

Important Risk Information for **ALL PATIENTS** using **Extraneal** (icodextrin) Peritoneal Dialysis Solution

The following risk information about **Extraneal** PD Solution pertains to **YOU**, whether or not you have diabetes.

How does this risk information pertain to me?

Hypothetical Scenario: You experience some type of injury, trauma, or health-related complication that causes you to **lose consciousness**.

When you receive medical attention from an emergency medical team (e.g., ambulance) or if you are hospitalized, it is **standard operating procedure for medical professionals to conduct routine blood glucose measurements** — whether or not you have diabetes.

What concerns should I have if someone checks my blood glucose levels?

ALL patients using **Extraneal** PD Solution can experience false high blood glucose readings for up to **14 days** after its last use, whether or not they have diabetes.

Extraneal PD Solution contains icodextrin. Icodextrin or its by-products, such as maltose, can cause some types of glucose monitors and/or test strips, including devices used at hospitals, clinics, and by emergency medical personnel, to give a **false high blood glucose reading**.

When hospitalized, **ALL** patients using **Extraneal** PD Solution should have their blood glucose levels tested at a hospital's central laboratory or with compatible glucometers and test strips.

For diabetic patients who routinely monitor their blood glucose levels, **ONLY** compatible glucometers and test strips should be used.

What are the risks associated with having a “false high blood glucose reading?”

■ **Situation A:** A true **NORMAL** blood glucose level appears as **high**.

POTENTIAL RISK—A false high blood glucose reading could lead to administration of insulin that is **NOT** needed.

■ **Situation B:** A true **LOW** blood glucose level appears as **normal**.

POTENTIAL RISK—A false high blood glucose reading may cause a healthcare provider to assume your blood glucose level is normal when your true (hospital central lab) blood glucose level is dangerously low. This can potentially trigger a life-threatening event if the appropriate steps are not taken to bring your blood glucose level back into normal range.

■ **BOTH** of these situations can potentially cause a life-threatening event or reaction such as:

- Loss of Consciousness (passing out)
- Coma
- Permanent Neurological Problems
- Death

How to use the Training Tool



- **Remove and fill-out** your **Wallet and Key Card** (located at the bottom of the left-interior panel of the carrier). Carry these cards with you at ALL times and show them when you receive medical care.
- **ALWAYS bring your Extraneal PD Solution Patient Kit with you** to **ALL** medical appointments — including visits to the emergency room or hospital.
- **ALL PATIENTS** receiving **Extraneal (icodextrin) Peritoneal Dialysis Solution** are at risk of having incorrect blood glucose readings which could potentially result in a life-threatening event, **whether or not they have diabetes**.
- **Extraneal PD Solution** can cause false high blood glucose readings for up to **14 days** after its last use.
- **Discuss this important information** about glucose monitors **with your family and friends**. In an emergency, they will be able to make sure the nurse or doctor knows of the potential for false high blood glucose readings.
- Wear one of your **Medical Wearables** to alert clinicians so they use the right kind of glucose monitor and test strips for you.

Bracelet



Necklace

Visit www.glucosesafety.com



High Risk Scenarios* where non glucose-specific monitors

AMBULANCE



False High Blood Glucose Reading Situations if non glu (applicable to ALL PATIENTS receiving Extraneal PD Solution, whether or not they have diabetes)

SITUATION A:

A TRUE NORMAL BLOOD GLUCOSE LEVEL APPEARS AS HIGH

May lead to an incorrect diagnosis of high blood glucose.

POTENTIAL RISK—A false high blood glucose reading could lead to administration of insulin that is **NOT** needed.

TRUE READING

100

(tested at hospital
central laboratory or with
a compatible glucometer
and test strip)

Your true blood glucose level
is within **normal** range.

SITUATION B:

A TRUE LOW BLOOD GLUCOSE LEVEL APPEARS AS NORMAL

May lead to an incorrect diagnosis of normal blood glucose.

POTENTIAL RISK—A false high blood glucose reading may cause a healthcare provider to assume your blood glucose level is normal when your true (hospital central lab) blood glucose level is dangerously low. This can potentially trigger a life-threatening event if the appropriate steps are not taken to bring your blood glucose level back into normal range.

TRUE READING

40

(tested at hospital
central laboratory or with
a compatible glucometer
and test strip)

Your true blood glucose level is
already **dangerously low**.

2

*The potential high risk scenarios highlighted are not comprehensive and are for illustrative purposes only.

s and test strips may be used

HOSPITAL



glucose-specific monitors are used



FALSE READING: TOO HIGH

Because you are using **Extraneal** (icodextrin) Peritoneal Dialysis Solution, your blood glucose level **appears too high**.

RESULT:

Insulin is administered causing your blood glucose to drop to **dangerously low levels** potentially triggering a life-threatening event or reaction.

Health Risks:

- ✓ loss of consciousness (passing out)
- ✓ coma
- ✓ permanent neurological problems
- ✓ death



FALSE READING: NORMAL

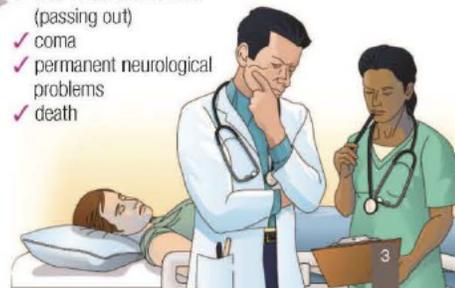
Because you are using **Extraneal** (icodextrin) Peritoneal Dialysis Solution, your blood glucose level **appears to be within normal range**.

RESULT:

Nothing is done because your blood glucose level appears to be normal.

Health Risks:

- ✓ loss of consciousness (passing out)
- ✓ coma
- ✓ permanent neurological problems
- ✓ death



Important Risk Information for **ALL** individuals who receive any type of professional medical care

Remember to complete these steps:

1 Whenever you receive medical care — whether it's a scheduled appointment, an outpatient procedure or an emergency room visit:

Tell doctors and nurses that:

- You are using **Extraneal** (icodextrin) Peritoneal Dialysis Solution
- Some glucose monitors and test strips may give a false high blood glucose reading due to your use of **Extraneal** PD solution
- Your blood glucose levels should be tested at a hospital's central laboratory or with compatible glucometers and test strips.



2 Bring your **Extraneal** PD Solution Patient Kit along with you and give it to the doctor or nurse treating you.

Why is this so important?

This kit contains important medical information for doctors, nurses and clinicians who provide care to you, other than those at your PD clinic, about the potential risk of false high blood glucose readings.



3 Discuss this important information about glucose monitors with your family and friends. In an emergency, they will be able to make sure the nurse or doctor knows of the potential for false high blood glucose readings.

4 Show your wallet card, to alert clinicians about the potential for incorrect blood glucose measurements. A wallet card is included here.

If you have any questions concerning glucose monitors and/or test strips, or glucose test results, call your PD nurse or the Emergency Contact number shown on the reverse side of your wallet card.

Patient Name	
I am using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution	
Use blood glucose readings obtained from laboratory-based methods <u>or</u> compatible glucometers and test strips. Use of incompatible glucometers and test strips may result in falsely elevated blood glucose readings for this patient.	
Name of Healthcare Provider	Phone Number
Name of PD Nurse/Center	Phone Number
Please visit www.glucosafety.com or contact 1-888-730-2543 (Option 1)	
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ATTENTION MEDICAL PROFESSIONAL
Patient is using **EXTRANEAL** (icodextrin) Peritoneal Dialysis Solution
Please visit www.glucosafety.com or contact 1-888-730-2543 (Option 1)

Important Risk Information for **INDIVIDUALS WITH DIABETES** and **PATIENTS** who **REGULARLY** measure their blood glucose (blood sugar) levels

- You or your PD nurse must confirm that your glucose monitor(s) and test strip(s) will provide an accurate reading when using **Extraneal** (icodextrin) Peritoneal Dialysis Solution.



- **DO NOT** use glucose monitors or test strips that utilize glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods. In addition, some blood glucose monitors or test strips that utilize glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Blood glucose measurements must be done with a method that does not cause maltose interference with test results.

ONLY compatible glucose monitors and test strips that use glucose-specific methods must be used by patients on Extraneal PD solution. To check the compatibility of a particular brand of glucometer and/or test strips, go to www.glucosafety.com

- Contact the manufacturer of your glucose monitor(s) and glucose test strip(s) and ask, *"Does icodextrin or maltose interfere with my glucose monitor or test strip results?"*
- **You must notify your PD nurse and dialysis doctor before you change** your home glucose monitor(s) or test strip(s).
- It's important to regularly check the compatibility of your glucose monitor(s) and test strips(s) while using **Extraneal** PD Solution. Also, if the manufacturer that makes your glucose monitor or test strips changes its methods of glucose measurement, be sure to contact your PD nurse or dialysis doctor to let them know. They can help you make the necessary adjustments.

Extraneal (icodextrin) PD Solution Patient Kit

Included Materials for both **YOU** and **YOUR CLINICIAN**

Because you are on **Extraneal** PD Solution, you'll soon receive an **Extraneal** PD Solution Patient Kit delivered to your home. Your PD nurse will show you a sample of the kit and explain the importance of all the components that are included. **If you require a replacement kit, please order one through your Baxter HomeCare Services Representative (HCSR) Team at 1-800-284-4060.**

The following patient materials can be found in the right pocket of the Patient Kit.



Medical Wearables: The included **bracelet** and **necklace** are designed to alert clinicians about the potential for incorrect blood glucose measurements.

Note: You should wear one or the other to alert clinicians so they use the right kind of glucose monitor and test strips for you.



The following Healthcare Professional materials can be found in the left pocket of the Patient Kit. Simply give these items to the nurse or physician who is seeing you.



Letters to Doctors, Nurses and Other Health Care Professionals (at a hospital or clinic): These letters describe the potential for interference with certain glucose monitors and test strips, and provide information to clinicians that let them know the appropriate test methods to use in order to safely measure blood glucose levels for patients on **Extraneal** PD solution.

Extraneal PD Solution Patient Chart Sticker and Hang Tag: These are tools your clinician may want to use to remind them about your history, and can be attached to your medical chart.

Medic Alert

If you are a MedicAlert member, or a member of another medical alert service, be sure to update your medical information to indicate that you use **Extraneal** PD solution. MedicAlert can be reached at **1-888-633-4298** or at www.medicalert.org

If you are not a member of a medical alert service, be sure to wear the **Extraneal** PD solution bracelet or necklace provided by Baxter in your **Extraneal** PD Solution Patient Kit — **this could help save your life.**

Important Risk Information for **Extraneal** (icodextrin) PD Solution

Do not use **Extraneal** PD solution if you:

- have a glycogen storage disease
- have severe lactic acidosis
- cannot tolerate maltose or isomaltose
- are allergic to cornstarch or icodextrin

Extraneal may not be right for you. Before using **Extraneal** PD solution, **tell your doctor** about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if **Extraneal** PD solution will harm your unborn baby
- are breast-feeding. It is not known if **Extraneal** PD solution passes into your breast milk

OR if you have:

- a condition that affects your nutrition
- low potassium levels in your blood
- low magnesium levels in your blood
- had stomach area:
 - surgery in the past 30 days
 - tumors
 - open wounds or an infection
 - hernia
- a lung or breathing problem
- high calcium levels in your blood
- had recent aortic graft surgery
- have certain bowel conditions including:
 - colostomy or ileostomy
 - frequent episodes of diverticulitis
 - inflammatory bowel disease

Extraneal can cause serious side effects, including:

- **Serious allergic reactions.** Tell your doctor or get medical help right away if you get any of these symptoms of a serious allergic reaction during treatment with **Extraneal**;
 - swelling of your face, eyes, lips, tongue or mouth
 - trouble swallowing or breathing
 - skin rash, hives, sores in your mouth, on your eyelids, or in your eyes
 - your skin blisters or peels

Common side effects of **Extraneal** PD solution include:

- Peritonitis, an infection in the peritoneal (abdominal) cavity, which is common in people on peritoneal dialysis. Tell your doctor right away if you have any pain, redness, fever, or cloudy drained fluid
- High blood pressure, nausea, headache, swelling, stomach area (abdomen) pain, chest pain, increased cough, upset stomach, flu-like symptoms, high blood sugar

These are not all the possible side effects of **Extraneal** PD solution. For more information, ask your doctor or dialysis center. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

For additional information please see the **Extraneal** PD Solution Medication Guide.

What you should know about **Extraneal** (icodextrin) PD Solution

1. It's important to do your dialysis daily as your doctor has prescribed. Use **Extraneal** PD solution for your long dwell (8 to 16 hours).
2. It's equally important to do your PD exchanges just as you were taught, every time.
3. To track your progress, record your weight, blood pressure, and how you feel every day. If there are any changes, be sure to let your PD nurse know right away.
4. Always keep some 1.5% dextrose solution at home. Why?
 - Using both 4.25% dextrose solution and **Extraneal** PD solution may cause you to become dehydrated, and your doctor may direct you to use 1.5% dextrose
 - If you are dehydrated, you may feel dizzy or become weak. Report these symptoms to your PD nurse or doctor immediately
5. Talk to you PD nurse or dialysis doctor about adding any medications to **Extraneal** PD solution.
6. If you're a Continuous Ambulatory Peritoneal Dialysis (CAPD) patient—and you notice a black-blue color in the drain line when switching from dextrose solutions to **Extraneal** PD solution—don't worry. The color appears when **Extraneal** PD solution mixes with leftover povidone-iodine in the **MiniCap** Disconnect Cap.
7. If you have insulin-dependent diabetes, pay attention to your insulin dose and monitor your blood glucose levels when using **Extraneal** PD Solution. Here are a few guidelines to follow:
 - Only use compatible glucose monitors and test strips to measure blood glucose levels
 - **See Important Risk Information about glucose monitors and test strips on Page 2 and the Extraneal Medication Guide for additional cautionary measures**
 - Be sure to check your blood glucose levels regularly
 - Discuss any changes needed to your current insulin dosage with your PD nurse or dialysis doctor. You may need to alter your insulin dose
8. **Extraneal** PD solution is best stored at room temperature: 68–77°F (20–25°C).
 - Until you use it, keep **Extraneal** PD solution in its moisture barrier overpouch in its carton
 - Avoid high heat (104°F/40°C) and protect from freezing





Glucose Monitor Manufacturers

The following list provides the names and contact information for manufacturers of today's most commonly used glucose monitors and test strips. It is included for reference only; you or your PD nurse need to contact the manufacturer to ensure that your monitor and test strips use a method that does not cause maltose interference with test results. **This list does not indicate that Baxter is recommending these products.** You or your PD nurse should call the manufacturer to verify if the monitor and/or test strip measures only glucose. **For further information, visit www.glucosafety.com.**

Manufacturer	Contact Information	
Abbott Diabetes Care	888-522-5226	www.abbottdiabetescare.com
AgaMatrix, Inc.	866-906-4197	www.agamatrix.com
Arkray	800-818-8877, Option #5	www.arkrayusa.com
Bayer Healthcare	800-348-8100	www.bayerdiabetes.com
Lifescan, Inc (Division of Johnson & Johnson)	800-227-8862	www.lifescan.com
NovaBiomedical	800-458-5813, 781-894-0800	www.novabiomedical.com
Roche Diagnostics	800-858-8072	www.roche-diagnostics.com www.accu-chek.com





www.baxter.com

Baxter Healthcare Corporation
Renal Division
One Baxter Parkway
Deerfield, IL 60015
1-888-798-2643

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07-27-74-131 03/15

The Baxter logo, consisting of the word "Baxter" in a bold, blue, sans-serif font.

Attachment 3

EXTRANEAL Patient Kit

EXTRANEAL PATIENT KIT: PATIENT LETTER

WARNING ATTENTION EXTRANEAL PD SOLUTION PATIENT

Important Information About EXTRANEAL (icodextrin) Peritoneal Dialysis (PD) Solution and Measuring Blood Sugar

This Patient Kit was designed to help inform you about the risk of false high blood glucose (sugar) readings while using **Extraneal** (icodextrin) Peritoneal Dialysis (PD) Solution. Regardless of your diabetic status, the following risk information about **Extraneal** PD Solution pertains to you, as it is standard operating procedure for emergency medical professionals to conduct routine blood glucose measurements—whether or not you have diabetes. Your PD nurse should have reviewed the content of this kit and what you need to know about the important precautions you need to take when your blood glucose is measured. **If your PD nurse has not reviewed this information with you, please call your PD nurse immediately.**

Bring your **Extraneal** Patient Kit with you whenever you receive medical attention, such as a scheduled appointment, emergency room, or any hospital visit. Make family and friends aware of the kit and tell them to bring your kit to the hospital if you cannot bring it yourself.

Extraneal PD Solution contains icodextrin. Icodextrin or its by-products, such as maltose, can cause some types of glucose monitors and/or test strips. This includes devices commonly used at hospitals/clinics and by emergency medical personnel.

A false (incorrect) high blood glucose reading could lead you to take too much insulin or wait too long to treat low blood sugar. You could have serious reactions including: **loss of consciousness (passing out), coma, permanent neurological problems or death.**

Do not use glucose monitors or test strips that contain: **glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ), glucose-dye-oxidoreductase (GDO), glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) (in some cases).**

Your Patient Kit contains materials to help you share important risk information with healthcare professionals that treat you. Please read the Patient Training Tool for important information you need to know while using **Extraneal** PD Solution.

Your kit also contains a bracelet and necklace. Please wear one of these alerts at all times to help protect you in emergency situations. In addition, you should have received a wallet card during training from your PD nurse. Extra wallet cards are provided in your Patient Kit. It is important that you fill out your wallet card and always carry this card with you to help share this risk information. Letters for you to give to the healthcare providers that see you outside of your PD clinic are also included.

If you lose any of the items or need a replacement, please order these items through your Baxter HomeCare Services Team at 1-800-284-4060.

If you monitor blood glucose values at home, you or your PD nurse should contact the manufacturer of your glucose monitor(s) and glucose test strip(s) and ask, “Does icodextrin or maltose interfere with my glucose monitor or test strip results?” For a list of toll free numbers for glucose monitor and test strip manufacturers, see page 12 in the Patient Training Tool or go to **www.glucosafety.com**.

Please see the enclosed Medication Guide for more safety information.

If you have any questions about **Extraneal** PD Solution or how to ensure that your blood glucose is measured safely, please contact your PD nurse immediately.

Sincerely,
Your Baxter Support Team

Please see full Important Risk Information on reverse side and enclosed Medication Guide.

EXTRANEAL PATIENT KIT: PATIENT LETTER (continued)

INDICATION FOR PATIENTS

EXTRANEAL is indicated for a single daily exchange for the long (8- to 16-hour) dwell during continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) for the management of end-stage renal disease.

EXTRANEAL is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high average or greater transport characteristics, as defined using the peritoneal equilibration test (PET).

IMPORTANT RISK INFORMATION FOR PATIENTS

EXTRANEAL PD solution contains maltose, which can react with certain blood glucose (blood sugar) monitors and test strips.

- Using **EXTRANEAL** PD solution may cause a false (incorrect) high blood sugar reading or may hide a blood sugar reading that is actually very low. This kind of false reading means that your blood sugar may really be too low even though the test says that it is normal or high. This can lead to dangerous side effects
- **Only use a glucose-specific monitor and test strips to monitor your blood glucose when being treated with EXTRANEAL and approximately 2 weeks after stopping EXTRANEAL**
- **If you are hospitalized or go to an emergency room, take your EXTRANEAL PD Solution Patient Kit along with you and tell the hospital staff that you use EXTRANEAL PD solution so that they use the right kind of blood glucose monitor and test strips for you**
- **Taking too much insulin or waiting too long to treat low blood sugar can cause you to have serious reactions including: loss of consciousness (passing out), coma, permanent neurological problems, or death**

Do not use **EXTRANEAL** PD solution if you:

- have a glycogen storage disease
- cannot tolerate maltose or isomaltose
- have severe lactic acidosis
- are allergic to cornstarch or icodextrin

EXTRANEAL may not be right for you. Before using **EXTRANEAL** PD solution, tell your doctor about all your medical conditions, including if you have:

- a condition that affects your nutrition
- low potassium levels in your blood
- low magnesium levels in your blood
- had stomach area:
 - surgery in the past 30 days
 - tumors
 - open wounds or an infection
 - hernia
- a lung or breathing problem
- high calcium levels in your blood
- had recent aortic graft surgery
- have certain bowel conditions including:
 - colostomy or ileostomy
 - frequent episodes of diverticulitis
 - inflammatory bowel disease
- are pregnant or plan to become pregnant. It is not known if **EXTRANEAL** PD solution will harm your unborn baby
- are breast-feeding. It is not known if **EXTRANEAL** PD solution passes into your breast milk

EXTRANEAL can cause serious side effects, including:

Serious allergic reactions. Tell your doctor or get medical help right away if you get any of these symptoms of a serious allergic reaction during treatment with **EXTRANEAL**:

- swelling of your face, eyes, lips, tongue or mouth
- trouble swallowing or breathing
- skin rash, hives, sores in your mouth, on your eyelids, or in your eyes
- your skin blisters and peels

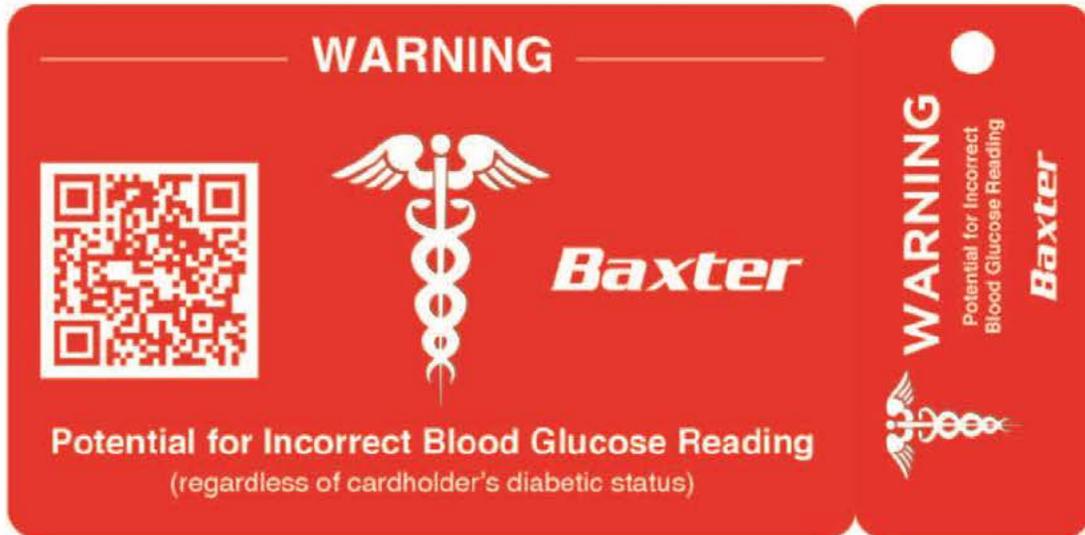
Common side effects of **EXTRANEAL** PD solution include:

- Peritonitis, an infection in the peritoneal (abdominal) cavity, which is common in people on peritoneal dialysis. Tell your doctor right away if you have any pain, redness, fever, or cloudy drained fluid
- High blood pressure, nausea, headache, swelling, stomach area (abdomen) pain, chest pain, increased cough, upset stomach, flu-like symptoms, high blood sugar

These are not all the possible side effects of **EXTRANEAL** PD solution. For more information, ask your doctor or dialysis center. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

For additional information please see the **EXTRANEAL** PD Solution Medication Guide.

EXTRANEAL PATIENT KIT: WALLET CARD:



<input type="text" value="Patient Name"/>	
is using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution	
Use blood glucose readings obtained from laboratory-based methods <u>or</u> compatible glucometers and test strips. Use of incompatible glucometers and test strips may result in falsely elevated blood glucose readings for this patient.	
Name of Nephrologist	Phone Number
<input type="text"/>	<input type="text"/>
Name of PD Nurse/Center	Phone Number
<input type="text"/>	<input type="text"/>
Please visit www.glucosafety.com or contact 1-888-736-2543 (Option 1)	
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ATTENTION MEDICAL PROFESSIONAL
Patient is using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution
Please visit www.glucosafety.com or contact 1-888-736-2543 (Option 1)

EXTRANEAL PATIENT KIT: WEARABLE ITEMS:

Bracelet

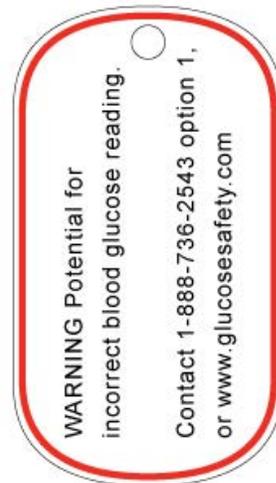


EXTRANEAL PATIENT KIT: WEARABLE ITEMS (continued):

Pendant

FRONT

BACK



EXTRANEAL PATIENT KIT: CHART STICKER

WARNING
Potential for Incorrect Blood Glucose Reading

Patient Name

**Is using Extraneal (icodextrin)
Peritoneal Dialysis Solution**

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Baxter International Inc. 07-27-74-133 08/15

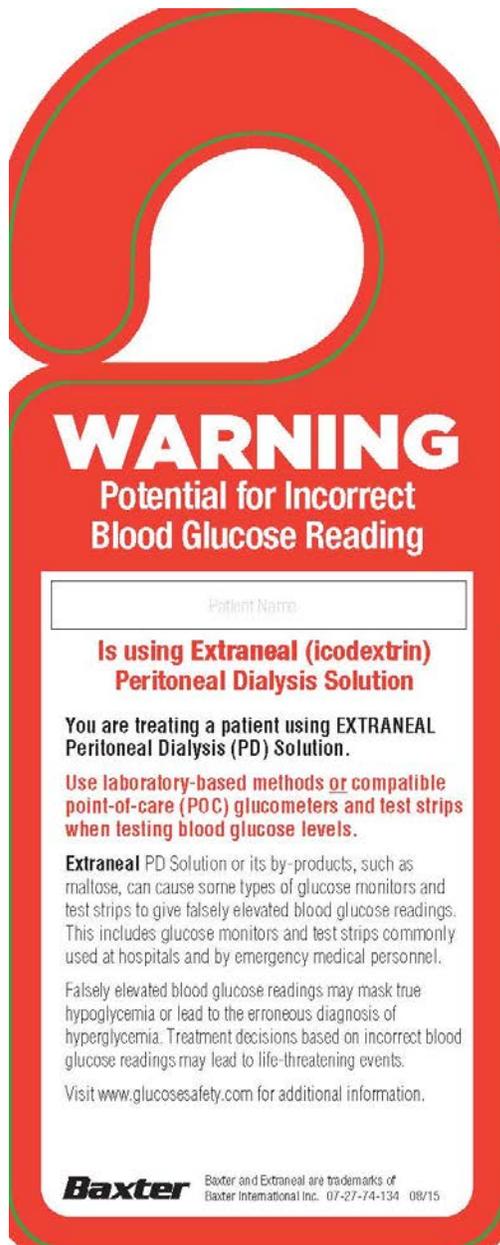
You are treating a patient using EXTRANEAL Peritoneal Dialysis (PD) Solution.
Use laboratory-based methods or compatible point-of-care (POC) glucometers and test strips when testing blood glucose levels.

Extraneal PD Solution or its by-products, such as maltose, can cause some types of glucose monitors and test strips to give falsely elevated blood glucose readings. This includes glucose monitors and test strips commonly used at hospitals and by emergency medical personnel.

Falsely elevated blood glucose readings may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia. Treatment decisions based on incorrect blood glucose readings may lead to life-threatening events.

Visit www.glucosafety.com for additional information.

EXTRANEAL PATIENT KIT: MAGNETIC HANG TAG



EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF

**WARNING
ATTENTION HOSPITAL PHYSICIAN**

**Potential For Incorrect Blood Glucose Reading in
Peritoneal Dialysis (PD) Patients**

Dear Hospital Physician,

Baxter Healthcare Corporation would like to notify you of Important Safety Information involving all patients who use **Extraneal** (icodextrin) Peritoneal Dialysis (PD) solution and who may require the use of blood glucose monitors and test strips.

You are treating a patient using **Extraneal** (icodextrin) peritoneal dialysis (PD) solution. When checking blood glucose levels, use laboratory-based methods or verify the point-of-care (POC) glucometer and test strips are compatible for use in patients using **Extraneal** PD Solution.

Extraneal (icodextrin) PD Solution or its by-products, such as maltose, can cause some types of glucose monitors and test strips to give falsely elevated blood glucose readings. This includes glucose monitors and test strips commonly used at hospitals and by emergency medical personnel.

Extraneal PD Solution can cause falsely elevated blood glucose readings for up to 14 days after its last use, regardless of a patient's diabetic status.

If your hospital uses electronic medical records, the potential for interference with blood glucose monitors and test strips needs to be entered in a prominent field.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH HAVING A "FALSELY ELEVATED BLOOD GLUCOSE READING?"

■ **SITUATION A:** A falsely elevated blood glucose reading may lead to the **erroneous diagnosis of hyperglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to administer insulin to the PD patient that is not needed.

■ **SITUATION B:** A falsely elevated blood glucose reading **may mask true hypoglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to assume that a PD patient's blood glucose level is normal when their true (hospital central lab) blood glucose level may be dangerously low. This could lead you or another clinician to **NOT** take the appropriate steps needed to bring the patient's blood glucose level back into a normal range.

■ **BOTH** of these situations can potentially cause a life-threatening event, such as:

- Loss of consciousness
- Coma
- Permanent neurological problems
- Death

For further information, refer to **Extraneal** (icodextrin) PD Solution Prescribing Information enclosed or visit www.glucosafety.com.

I hope this information is helpful to you. If you have additional questions about **Extraneal** PD Solution, please contact Baxter's Renal Clinical Helpline at 1-888-736-2543 (option 1).

Sincerely,

James A. Sloand, MD
Senior Medical Director, Medical Affairs
Baxter Healthcare Corporation

**Please see full Important Safety Information, including boxed warning,
on reverse side and enclosed Full Prescribing Information.**

EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

Indications

Extraneal (icodextrin) Peritoneal Dialysis (PD) solution is indicated for a single daily exchange for the long (8 to 16 hour) dwell during Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) for the management of End-Stage Renal Disease (ESRD). **Extraneal** solution is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high-average or greater transport characteristics, as defined using the Peritoneal Equilibration Test (PET).

Important Risk Information:

WARNING: UNRECOGNIZED HYPOGLYCEMIA RESULTING FROM DRUG-DEVICE INTERACTION

- Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of EXTRANEAL (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.
- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

- **Extraneal** (icodextrin) is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with pre-existing severe lactic acidosis.
- **Extraneal** PD solution is intended for intraperitoneal administration only. Not for intravenous injection. Aseptic technique should be used throughout the peritoneal dialysis procedure.
- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using **Extraneal** PD solution.
- Serious hypersensitivity reactions to **Extraneal** PD solution have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Institute appropriate therapeutic countermeasures as clinically indicated.
- Effective use of **Extraneal** PD solution may be compromised in patients with abdominal conditions predisposing them to complications of peritoneal dialysis, including infection.
- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with **Extraneal** PD solution. Monitor blood glucose and adjust insulin, if needed.
- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.
- In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients and more common in **Extraneal** PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse event for **Extraneal** PD solution patients was skin rash.
- Please see Package Insert for full Prescribing Information.

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EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

WARNING
ATTENTION HOSPITAL ADMINISTRATION STAFF

**Potential For Incorrect Blood Glucose Reading in
Peritoneal Dialysis (PD) Patients**

Dear Hospital Administration Staff,

Baxter Healthcare Corporation would like to notify you of Important Safety Information involving all patients who use **Extraneal** (icodextrin) Peritoneal Dialysis (PD) solution and who may require the use of blood glucose monitors and test strips.

You are treating a patient using **Extraneal** (icodextrin) peritoneal dialysis (PD) solution. When checking blood glucose levels, use laboratory-based methods or verify the point-of-care (POC) glucometer and test strips are compatible for use in patients using **Extraneal** PD Solution.

Extraneal (icodextrin) PD Solution or its by-products, such as maltose, can cause some types of glucose monitors and test strips to give falsely elevated blood glucose readings. This includes glucose monitors and test strips commonly used at hospitals and by emergency medical personnel.

Extraneal PD Solution can cause falsely elevated blood glucose readings for up to 14 days after its last use, regardless of a patient's diabetic status.

If your hospital uses electronic medical records, the potential for interference with blood glucose monitors and test strips needs to be entered in a prominent field.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH HAVING A "FALSELY ELEVATED BLOOD GLUCOSE READING?"

■ **SITUATION A:** A falsely elevated blood glucose reading may lead to the **erroneous diagnosis of hyperglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to administer insulin to the PD patient that is not needed.

■ **SITUATION B:** A falsely elevated blood glucose reading **may mask true hypoglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to assume that a PD patient's blood glucose level is normal when their true (hospital central lab) blood glucose level may be dangerously low. This could lead you or another clinician to **NOT** take the appropriate steps needed to bring the patient's blood glucose level back into a normal range.

■ **BOTH** of these situations can potentially cause a life-threatening event, such as:

- Loss of consciousness
- Coma
- Permanent neurological problems
- Death

For further information, refer to **Extraneal** (icodextrin) PD Solution Prescribing Information enclosed or visit www.glucosafety.com.

I hope this information is helpful to you. If you have additional questions about **Extraneal** PD Solution, please contact Baxter's Renal Clinical Helpline at 1-888-736-2543 (option 1).

Sincerely,

James A. Sloand, MD
Senior Medical Director, Medical Affairs
Baxter Healthcare Corporation

**Please see full Important Safety Information, including boxed warning,
on reverse side and enclosed Full Prescribing Information.**

EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

Indications

Extraneal (icodextrin) Peritoneal Dialysis (PD) solution is indicated for a single daily exchange for the long (8 to 16 hour) dwell during Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) for the management of End-Stage Renal Disease (ESRD). **Extraneal** solution is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high-average or greater transport characteristics, as defined using the Peritoneal Equilibration Test (PET).

Important Risk Information:

WARNING: UNRECOGNIZED HYPOGLYCEMIA RESULTING FROM DRUG-DEVICE INTERACTION

- Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of EXTRANEAL (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.
- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

- **Extraneal** (icodextrin) is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with pre-existing severe lactic acidosis.
- **Extraneal** PD solution is intended for intraperitoneal administration only. Not for intravenous injection. Aseptic technique should be used throughout the peritoneal dialysis procedure.
- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using **Extraneal** PD solution.
- Serious hypersensitivity reactions to **Extraneal** PD solution have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Institute appropriate therapeutic countermeasures as clinically indicated.
- Effective use of **Extraneal** PD solution may be compromised in patients with abdominal conditions predisposing them to complications of peritoneal dialysis, including infection.
- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with **Extraneal** PD solution. Monitor blood glucose and adjust insulin, if needed.
- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.
- In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients and more common in **Extraneal** PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse event for **Extraneal** PD solution patients was skin rash.
- Please see Package Insert for full Prescribing Information.

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EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

**WARNING
ATTENTION LABORATORY SERVICES**

**Potential For Incorrect Blood Glucose Reading in
Peritoneal Dialysis (PD) Patients**

Dear Laboratory Services,

Baxter Healthcare Corporation would like to notify you of Important Safety Information involving all patients who use **Extraneal** (icodextrin) Peritoneal Dialysis (PD) solution and who may require the use of blood glucose monitors and test strips.

You are treating a patient using **Extraneal** (icodextrin) peritoneal dialysis (PD) solution. When checking blood glucose levels, use laboratory-based methods or verify the point-of-care (POC) glucometer and test strips are compatible for use in patients using **Extraneal** PD Solution.

Extraneal (icodextrin) PD Solution or its by-products, such as maltose, can cause some types of glucose monitors and test strips to give falsely elevated blood glucose readings. This includes glucose monitors and test strips commonly used at hospitals and by emergency medical personnel.

Extraneal PD Solution can cause falsely elevated blood glucose readings for up to 14 days after its last use, regardless of a patient's diabetic status.

If your hospital uses electronic medical records, the potential for interference with blood glucose monitors and test strips needs to be entered in a prominent field.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH HAVING A "FALSELY ELEVATED BLOOD GLUCOSE READING?"

■ **SITUATION A:** A falsely elevated blood glucose reading may lead to the **erroneous diagnosis of hyperglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to administer insulin to the PD patient that is not needed.

■ **SITUATION B:** A falsely elevated blood glucose reading **may mask true hypoglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to assume that a PD patient's blood glucose level is normal when their true (hospital central lab) blood glucose level may be dangerously low. This could lead you or another clinician to **NOT** take the appropriate steps needed to bring the patient's blood glucose level back into a normal range.

■ **BOTH** of these situations can potentially cause a life-threatening event, such as:

- Loss of consciousness
- Coma
- Permanent neurological problems
- Death

For further information, refer to **Extraneal** (icodextrin) PD Solution Prescribing Information enclosed or visit www.glucosafety.com.

I hope this information is helpful to you. If you have additional questions about **Extraneal** PD Solution, please contact Baxter's Renal Clinical Helpline at 1-888-736-2543 (option 1).

Sincerely,

James A. Sloand, MD
Senior Medical Director, Medical Affairs
Baxter Healthcare Corporation

**Please see full Important Safety Information, including boxed warning,
on reverse side and enclosed Full Prescribing Information.**

EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

Indications

Extraneal (icodextrin) Peritoneal Dialysis (PD) solution is indicated for a single daily exchange for the long (8 to 16 hour) dwell during Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) for the management of End-Stage Renal Disease (ESRD). **Extraneal** solution is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high-average or greater transport characteristics, as defined using the Peritoneal Equilibration Test (PET).

Important Risk Information:

WARNING: UNRECOGNIZED HYPOGLYCEMIA RESULTING FROM DRUG-DEVICE INTERACTION

- Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of EXTRANEAL (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.
- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

- **Extraneal** (icodextrin) is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with pre-existing severe lactic acidosis.
- **Extraneal** PD solution is intended for intraperitoneal administration only. Not for intravenous injection. Aseptic technique should be used throughout the peritoneal dialysis procedure.
- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using **Extraneal** PD solution.
- Serious hypersensitivity reactions to **Extraneal** PD solution have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Institute appropriate therapeutic countermeasures as clinically indicated.
- Effective use of **Extraneal** PD solution may be compromised in patients with abdominal conditions predisposing them to complications of peritoneal dialysis, including infection.
- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with **Extraneal** PD solution. Monitor blood glucose and adjust insulin, if needed.
- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.
- In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients and more common in **Extraneal** PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse event for **Extraneal** PD solution patients was skin rash.
- Please see Package Insert for full Prescribing Information.

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EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

**WARNING
ATTENTION HOSPITAL NURSE**

**Potential For Incorrect Blood Glucose Reading in
Peritoneal Dialysis (PD) Patients**

Dear Hospital Nurse,

Baxter Healthcare Corporation would like to notify you of Important Safety Information involving all patients who use **Extraneal** (icodextrin) Peritoneal Dialysis (PD) solution and who may require the use of blood glucose monitors and test strips.

You are treating a patient using **Extraneal** (icodextrin) peritoneal dialysis (PD) solution. When checking blood glucose levels, use laboratory-based methods or verify the point-of-care (POC) glucometer and test strips are compatible for use in patients using **Extraneal** PD Solution.

Extraneal (icodextrin) PD Solution or its by-products, such as maltose, can cause some types of glucose monitors and test strips to give falsely elevated blood glucose readings. This includes glucose monitors and test strips commonly used at hospitals and by emergency medical personnel.

Extraneal PD Solution can cause falsely elevated blood glucose readings for up to 14 days after its last use, regardless of a patient's diabetic status.

If your hospital uses electronic medical records, the potential for interference with blood glucose monitors and test strips needs to be entered in a prominent field.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH HAVING A "FALSELY ELEVATED BLOOD GLUCOSE READING?"

■ **SITUATION A:** A falsely elevated blood glucose reading may lead to the **erroneous diagnosis of hyperglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to administer insulin to the PD patient that is not needed.

■ **SITUATION B:** A falsely elevated blood glucose reading **may mask true hypoglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to assume that a PD patient's blood glucose level is normal when their true (hospital central lab) blood glucose level may be dangerously low. This could lead you or another clinician to **NOT** take the appropriate steps needed to bring the patient's blood glucose level back into a normal range.

■ **BOTH** of these situations can potentially cause a life-threatening event, such as:

- Loss of consciousness
- Coma
- Permanent neurological problems
- Death

For further information, refer to **Extraneal** (icodextrin) PD Solution Prescribing Information enclosed or visit www.glucosafety.com.

I hope this information is helpful to you. If you have additional questions about **Extraneal** PD Solution, please contact Baxter's Renal Clinical Helpline at 1-888-736-2543 (option 1).

Sincerely,

James A. Sloand, MD
Senior Medical Director, Medical Affairs
Baxter Healthcare Corporation

**Please see full Important Safety Information, including boxed warning,
on reverse side and enclosed Full Prescribing Information.**

EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

Indications

Extraneal (icodextrin) Peritoneal Dialysis (PD) solution is indicated for a single daily exchange for the long (8 to 16 hour) dwell during Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) for the management of End-Stage Renal Disease (ESRD). **Extraneal** solution is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high-average or greater transport characteristics, as defined using the Peritoneal Equilibration Test (PET).

Important Risk Information:

WARNING: UNRECOGNIZED HYPOGLYCEMIA RESULTING FROM DRUG-DEVICE INTERACTION

- Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using EXTRANEAL (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of EXTRANEAL (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of EXTRANEAL (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of EXTRANEAL (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.
- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

- **Extraneal** (icodextrin) is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with pre-existing severe lactic acidosis.
- **Extraneal** PD solution is intended for intraperitoneal administration only. Not for intravenous injection. Aseptic technique should be used throughout the peritoneal dialysis procedure.
- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using **Extraneal** PD solution.
- Serious hypersensitivity reactions to **Extraneal** PD solution have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Institute appropriate therapeutic countermeasures as clinically indicated.
- Effective use of **Extraneal** PD solution may be compromised in patients with abdominal conditions predisposing them to complications of peritoneal dialysis, including infection.
- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with **Extraneal** PD solution. Monitor blood glucose and adjust insulin, if needed.
- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.
- In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients and more common in **Extraneal** PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse event for **Extraneal** PD solution patients was skin rash.
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EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

**WARNING
ATTENTION HOSPITAL PHARMACY**

**Potential For Incorrect Blood Glucose Reading in
Peritoneal Dialysis (PD) Patients**

Dear Hospital Pharmacy,

Baxter Healthcare Corporation would like to notify you of Important Safety Information involving all patients who use **Extraneal** (icodextrin) Peritoneal Dialysis (PD) solution and who may require the use of blood glucose monitors and test strips.

You are treating a patient using **Extraneal** (icodextrin) peritoneal dialysis (PD) solution. When checking blood glucose levels, use laboratory-based methods or verify the point-of-care (POC) glucometer and test strips are compatible for use in patients using **Extraneal** PD Solution.

Extraneal (icodextrin) PD Solution or its by-products, such as maltose, can cause some types of glucose monitors and test strips to give falsely elevated blood glucose readings. This includes glucose monitors and test strips commonly used at hospitals and by emergency medical personnel.

Extraneal PD Solution can cause falsely elevated blood glucose readings for up to 14 days after its last use, regardless of a patient's diabetic status.

If your hospital uses electronic medical records, the potential for interference with blood glucose monitors and test strips needs to be entered in a prominent field.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH HAVING A "FALSELY ELEVATED BLOOD GLUCOSE READING?"

■ **SITUATION A:** A falsely elevated blood glucose reading may lead to the **erroneous diagnosis of hyperglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to administer insulin to the PD patient that is not needed.

■ **SITUATION B:** A falsely elevated blood glucose reading **may mask true hypoglycemia.**

POTENTIAL RISK — A falsely elevated blood glucose reading could cause you or another clinician to assume that a PD patient's blood glucose level is normal when their true (hospital central lab) blood glucose level may be dangerously low. This could lead you or another clinician to **NOT** take the appropriate steps needed to bring the patient's blood glucose level back into a normal range.

■ **BOTH** of these situations can potentially cause a life-threatening event, such as:

- Loss of consciousness
- Coma
- Permanent neurological problems
- Death

For further information, refer to **Extraneal** (icodextrin) PD Solution Prescribing Information enclosed or visit www.glucosafety.com.

I hope this information is helpful to you. If you have additional questions about **Extraneal** PD Solution, please contact Baxter's Renal Clinical Helpline at 1-888-736-2543 (option 1).

Sincerely,

James A. Sloand, MD
Senior Medical Director, Medical Affairs
Baxter Healthcare Corporation

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EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

Indications

Extraneal (icodextrin) Peritoneal Dialysis (PD) solution is indicated for a single daily exchange for the long (8 to 16 hour) dwell during Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) for the management of End-Stage Renal Disease (ESRD). **Extraneal** solution is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high-average or greater transport characteristics, as defined using the Peritoneal Equilibration Test (PET).

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- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

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EXTRANEAL PATIENT KIT: EXTRANEAL PACKAGE INSERT

Refer to NDA 21-312/S-028 or DailyMed for current Package Insert.

EXTRANEAL PATIENT KIT: EXTRANEAL MEDICATION GUIDE

Refer to NDA 21-321/S-032 or DailyMed for current Medication Guide.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
10/16/2015

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