

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 pyrroloquinolinequinone (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
Ascensia Diabetes Care	800-348-8100	www.asoensia.com
Lifescan, Inc (Division of Johnson & Johnson)	800-227-8882	www.lifescan.com
Nipro Diagnostics	800-803-6025	www.niprodiagnostics.com
NovaBiomedical	800-458-5813, 781-894-0800	www.novabiomedical.com
Prodigy Diabetes Care	800-243-2636	customercare@prodigymeter.com
Roche Diagnostics	800-858-8072	www.roche-diagnostics.com www.aocu-ohk.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.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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