Using Extraneal (icodextrin) Peritoneal Dialysis Solution

PATIENT TRAINING TOOL
Important Risk Information for ALL PATIENTS using Extraneal (icodextrin) Peritoneal Dialysis Solution

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. Icdexrin 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 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.
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.

Visit www.glucosesafety.com
High Risk Scenarios* where non glucose-specific monitors

False High Blood Glucose Reading Situations if non glucose-specific monitors are used

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

Your true blood glucose level is already dangerously low.

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

- Patient Letter
- Patient Training Tool
- Wallet Card and Key Card

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 your 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:
   - Use compatible glucose monitors and test strips to measure blood glucose levels.
   - 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.

   - 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.glucosesafety.com.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Contact Information</th>
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<tbody>
<tr>
<td>Abbott Diabetes Care</td>
<td>888-522-5226</td>
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<tr>
<td>AgaMatrix, Inc.</td>
<td>866-906-4197</td>
</tr>
<tr>
<td>Arkray</td>
<td>800-818-6877, Option #5</td>
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<tr>
<td>Bayer Healthcare</td>
<td>800-348-8100</td>
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<tr>
<td>Litescan, Inc. (Division of Johnson &amp; Johnson)</td>
<td>800-227-8862</td>
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<tr>
<td>NovoBiomedical</td>
<td>800-458-5613, 781-894-0900</td>
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<tr>
<td>Roche Diagnostics</td>
<td>800-888-8072</td>
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www.abbottdiabetescare.com
www.agamatrix.com
www.arkrayusa.com
www.bayerdiabetes.com
www.litescan.com
www.novobiomedical.com
www.roche-diagnostics.com
www.accu-chek.com