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.glucosesafety.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.

Reference ID: 3834142

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.

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EXTRANEAL PATIENT KIT: WALLET CARD:

EXTRANEAL PATIENT KIT: WEARABLE ITEMS:

Bracelet

Reference ID: 3834142

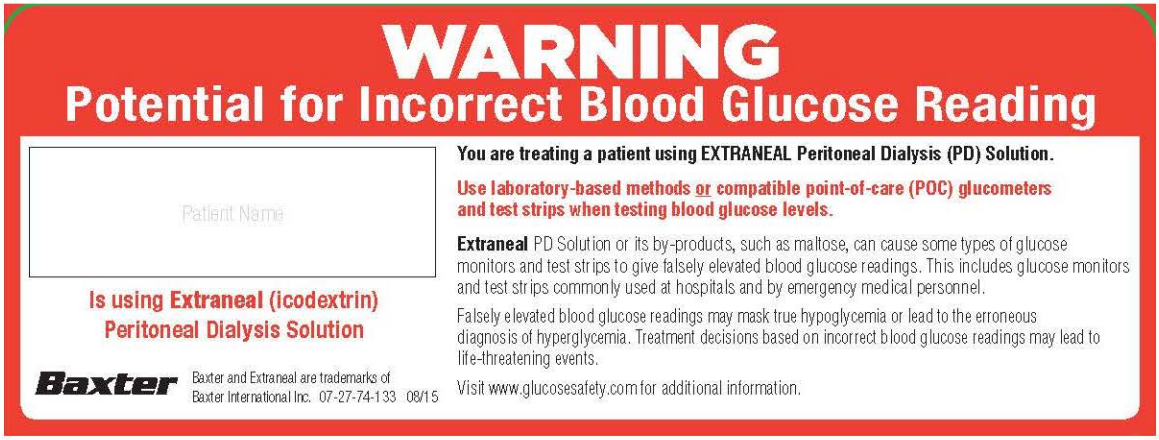
EXTRANEAL PATIENT KIT: WEARABLE ITEMS (continued):

Pendant

FRONT **BACK**

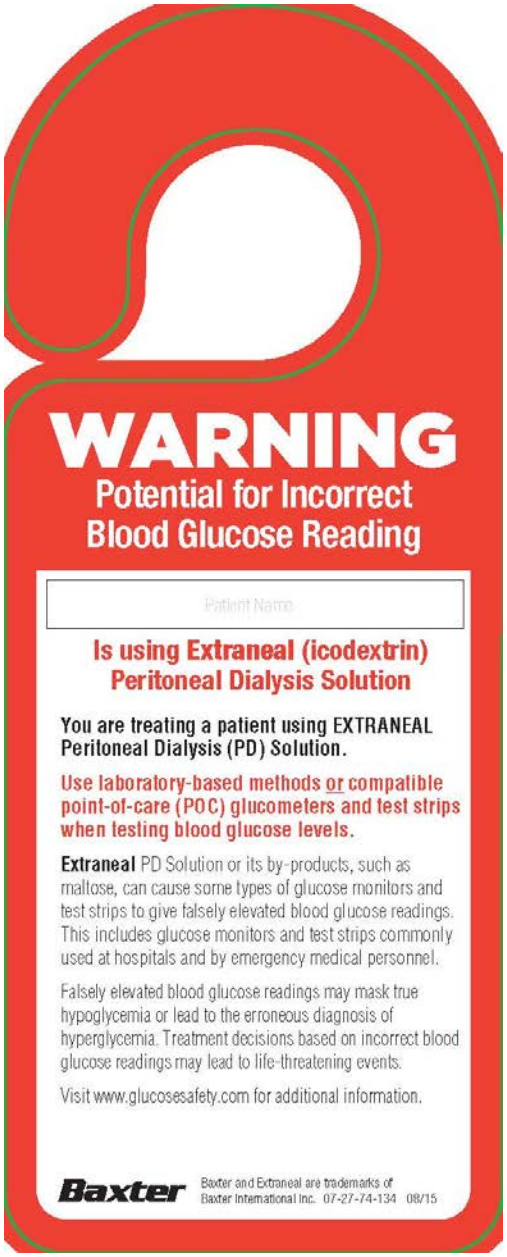
Reference ID: 3834142

EXTRANEAL PATIENT KIT: CHART STICKER



Reference ID: 3834142

EXTRANEAL PATIENT KIT: MAGNETIC HANG TAG



Reference ID: 3834142

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.glucosesafety.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 ≥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 Administation 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.glucosesafety.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 ≥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.glucosesafety.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).

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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.

- **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.
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- 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.
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- In clinical trials, the most frequently reported adverse events occurring in ≥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.

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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.glucosesafety.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 ≥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 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?"

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- Loss of consciousness
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- Permanent neurological problems
- Death

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

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James A. Sloand, MD
Senior Medical Director, Medical Affairs
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EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF (continued)

Indications

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