Attachment 3

Extraneal Patient Kit

EXTRANEAL PATIENT KIT: DEAR PATIENT LETTER

Attention EXTRANEAL Patient

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

Dear Patient,

This patient kit has been created to protect you from false blood glucose (sugar) readings while using **EXTRANEAL** (icodextrin) Peritoneal Dialysis (PD) solution. Your PD nurse should have reviewed the contents of this kit, and what you need to do when measuring blood sugar. If your PD nurse has not reviewed this information with you, be sure to talk about this at your next regular visit.

EXTRANEAL PD solution contains maltose, which can react with certain blood glucose 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 can happen if you use a glucose monitor or test strips that use glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreaductase (GDO) methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method must not be used. Use of these methods may result in falsely elevated blood glucose readings in patients using **EXTRANEAL** (icodextrin) due to maltose interference at any time during treatment with **EXTRANEAL** PD solution or within approximately 2 weeks (14 days) after you stop treatment with **EXTRANEAL** PD solution. A 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.

So which items are important to use and wear and why?

You should have received a wallet card during training from your PD nurse. If you always keep this card in your wallet, it can help you to share the risk information with other clinicians you are seeing, or if you are hospitalized. Please always carry it with you. In addition, use this card to inform other doctors and nurses treating you about your potentially falsely high blood glucose readings.

Whenever you receive medical care – whether it's a scheduled appointment, an outpatient procedure or an emergency room visit – be sure to bring your **EXTRANEAL** PD Solution Patient Kit along with you. The information contained in your **patient kit** will explain the glucose test issue to the different hospital departments. Please be sure to make family and friends aware of the kit, and tell them to bring it to the hospital in cases where you can't take it yourself.

The kit also contains important medical information for doctors, nurses and clinicians who provide care to you, other than those at your PD clinic. That's why it's so important to take the kit with you when receiving medical care. Simply give it to the nurse or physician who is seeing you.

Also included in the kit are a **bracelet** and a **necklace** that are designed to alert clinicians about the potential for incorrect blood glucose measurements. You should wear one or the other to alert clinicians in an emergency or if you are hospitalized.

Should you lose any of the items or need a replacement, please order these items through your Baxter HomeCare Services Representative (HCSR) Team. Your safety is very important to us. Please use the items as recommended.

We hope this information is helpful to you. If you have additional questions about **EXTRANEAL** PD solution or measuring blood sugar, please contact your PD nurse.

Sincerely,

Your Baxter Support Team

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

This letter is part of an FDA approved REMS

EXTRANEAL PATIENT KIT: DEAR 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:

WARNING
Potential for Incorrect Blood Glucose Reading

ONLY use glucose-specific monitors and test strips on this peritoneal dialysis patient. Some glucose monitors are not glucose-specific and cannot tell the difference between glucose and other sugars in the blood (e.g., maltose, a metabolite of icodextrin). Use laboratory-based methods, if available or a glucose-specific monitor and test strips.

DO NOT use glucose monitors or test strips that utilize glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method must not be used. Use of these methods may result in falsely elevated blood glucose readings in patients using **Extraneal** (icodextrin) Peritoneal Dialysis Solution due to maltose interference. 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.glucosesafety.com for additional information, including a glucose monitor compatibility list.

Baxter

See reverse side for warnings

Patient Name

Is using EXTRANEAL (icodextrin) peritoneal dialysis solution

Emergency Contact Information

Nephrologist _____ ( ) _____

PD Nurse/Center _____ ( ) _____

Other Contact _____ ( ) _____

EXTRANEAL PATIENT KIT: WEARABLE ITEMS:

Bracelet

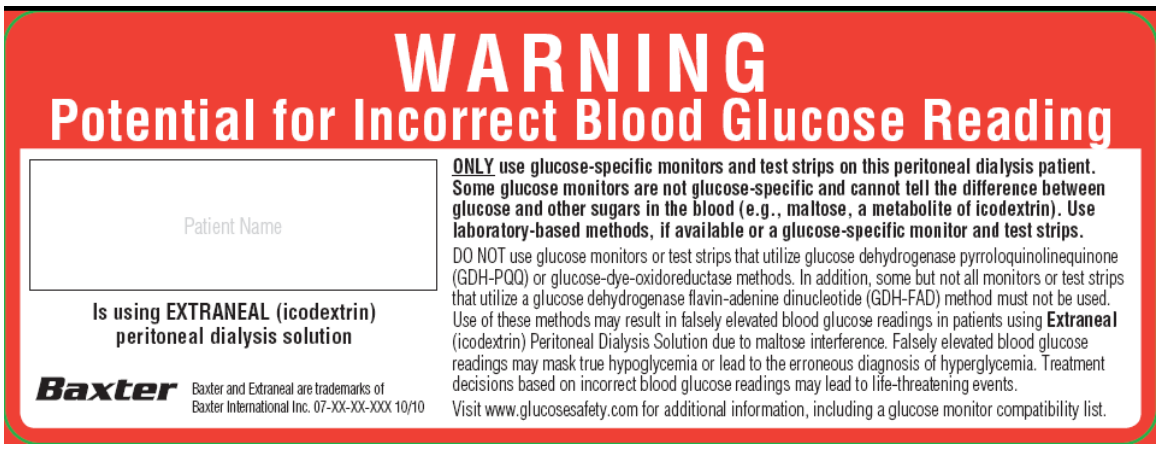
EXTRANEAL PATIENT KIT: WEARABLE ITEMS (continued):

Pendant

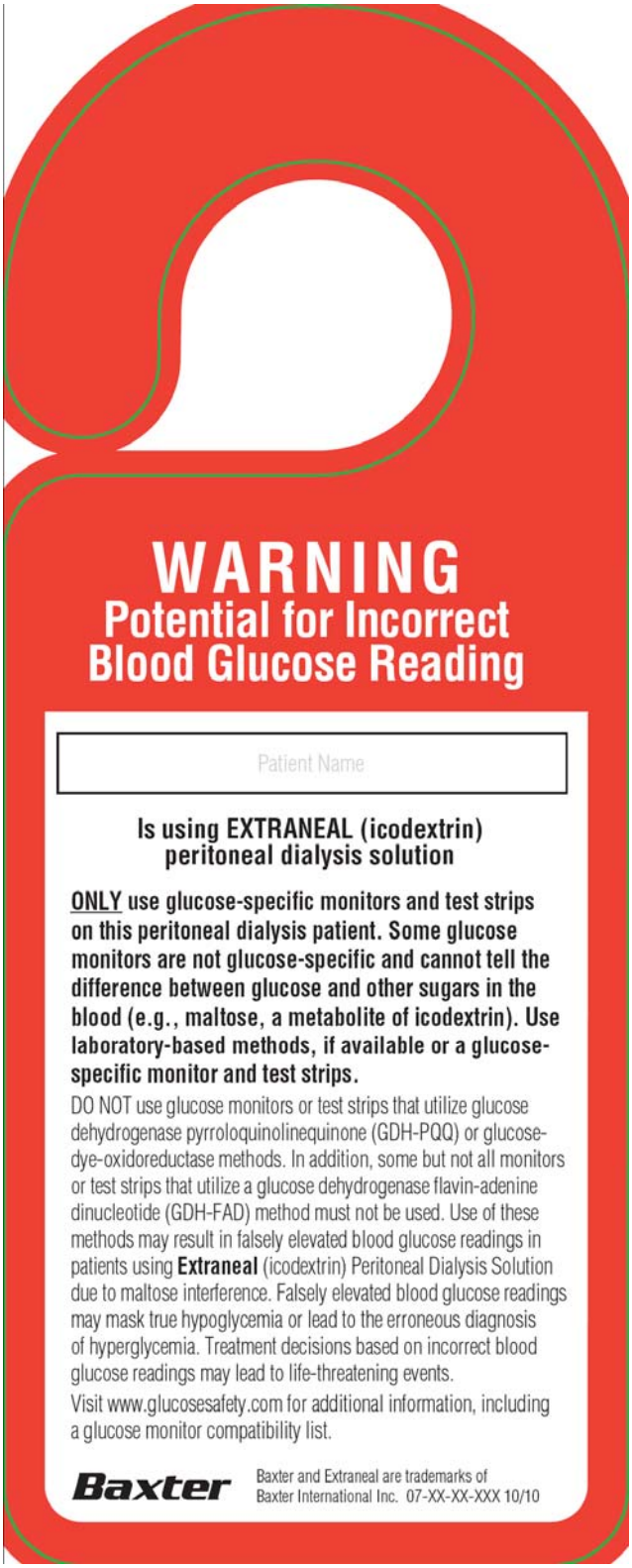
FRONT

BACK

EXTRANEAL PATIENT KIT: CHART STICKER



EXTRANEAL PATIENT KIT: MAGNETIC HANG TAG



EXTRANEAL PATIENT KIT: LETTERS TO HOSPITAL STAFF

Attention Hospital Physician

WARNING

Potential For Incorrect Blood Glucose Reading

November 2010

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.

Patients using EXTRANEAL (icodextrin) peritoneal dialysis solution may have incorrect blood glucose results when using particular blood glucose monitors and test strips.

ONLY use glucose monitors and test strips that are glucose-specific. Some glucose monitors are not glucose-specific and cannot tell the difference between glucose and other sugars in the blood (e.g., maltose, a metabolite of icodextrin). Use laboratory-based methods, if available or a glucose-specific monitor and test strips. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used. Visit www.glucosesafety.com for additional information including a glucose monitor compatibility list.

The term "glucose-specific" applies to monitors or test strips that are not affected by the presence of maltose or certain other sugars. Because **EXTRANEAL** (icodextrin) PD solution results in elevated blood levels of maltose, only glucose-specific monitors and test strips should be used.

DO NOT use glucose monitors or test strips that utilize glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO) methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method must not be used. Use of these methods may result in falsely elevated blood glucose readings in patients using **EXTRANEAL** (icodextrin) due to maltose interference. A blood glucose reading with these monitors that appears to be within the normal range in a patient on **EXTRANEAL** (icodextrin) may mask true hypoglycemia (low blood sugar). This would cause a patient or health care professional not to take the appropriate steps to bring the blood sugar into a normal range. A falsely elevated blood glucose reading could cause a patient to get more insulin than needed. Both of these situations can lead to life-threatening events, including loss of consciousness, coma, permanent neurological damage or death.

Additional considerations for patients who use **EXTRANEAL** (icodextrin) PD solution:

1. Discontinuing **EXTRANEAL** (icodextrin) PD solution use will not immediately address the risk for the potential interference with glucose monitors. Falsely elevated glucose levels may result up to two weeks following cessation of **EXTRANEAL** (icodextrin).
2. To determine what type of method is used for monitoring glucose levels, review the labeling for BOTH the glucose monitor and the test strips used. If in doubt, contact the manufacturer of the glucose monitors and test strips to determine the method that is used.
3. If your hospital uses electronic medical records, the above information describing the potential for interference with blood glucose monitors or test strips needs to be entered in a suitable field that is readily apparent to all users.

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** (icodextrin) PD solution, please contact your Baxter Renal Representative.

Sincerely,

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

Please see Important Risk Information on reverse side and enclosed Full Prescribing Information.

This letter is part of an FDA approved REMS

IMPORTANT RISK INFORMATION
EXTRANEAL (icodextrin) Peritoneal Dialysis (PD) Solution

Dangerous 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, see **PRECAUTIONS/Drug/Laboratory Test Interactions**). 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.

Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

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 HelpLine 1-888-RENAL-HELP or visit www.glucosesafety.com.

EXTRANEAL PD solution is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with pre-existing severe lactic acidosis, and in patients with glycogen storage disease.

EXTRANEAL PD solution is intended for intraperitoneal administration only. Not for intravenous injection.

Rarely, serious hypersensitivity reactions to EXTRANEAL have been reported, such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme, and leukocytoclastic vasculitis. If a serious reaction is suspected, discontinue EXTRANEAL and institute appropriate treatment as clinically indicated.

Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment.

A patient's volume status should be carefully monitored to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock. An accurate fluid balance record must be kept and the patient's body weight monitored.

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. Additional adverse reactions have been reported in the post-marketing setting and are detailed in the full prescribing information.

General Peritoneal Dialysis-Related
Encapsulating Peritoneal Sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including EXTRANEAL PD solution. Infrequent but fatal outcomes have been reported.

Aseptic technique should be used throughout the peritoneal dialysis procedure to reduce the possibility of infection, such as peritonitis.

Fluid status, hematologic indices, blood chemistry, and electrolyte concentrations, including calcium, potassium, sodium, magnesium and bicarbonate, should be monitored periodically. Abnormalities in any of these parameters should be treated promptly under the care of a physician.

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is to drain the peritoneal dialysis solution from the peritoneal cavity.

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

Please see full prescribing information.

Attention Hospital Nurse

WARNING

Potential For Incorrect Blood Glucose Reading

November 2010

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.

Patients using EXTRANEAL (icodextrin) peritoneal dialysis solution may have incorrect blood glucose results when using particular blood glucose monitors and test strips.

ONLY use glucose monitors and test strips that are glucose-specific. Some glucose monitors are not glucose-specific and cannot tell the difference between glucose and other sugars in the blood (e.g., maltose, a metabolite of icodextrin). Use laboratory-based methods, if available or a glucose-specific monitor and test strips. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used. Visit www.glucosesafety.com for additional information including a glucose monitor compatibility list.

The term "glucose-specific" applies to monitors or test strips that are not affected by the presence of maltose or certain other sugars. Because **EXTRANEAL** (icodextrin) PD solution results in elevated blood levels of maltose, only glucose-specific monitors and test strips should be used.

DO NOT use glucose monitors or test strips that utilize glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO) methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method must not be used. Use of these methods may result in falsely elevated blood glucose readings in patients using **EXTRANEAL** (icodextrin) due to maltose interference. A blood glucose reading with these monitors that appears to be within the normal range in a patient on **EXTRANEAL** (icodextrin) may mask true hypoglycemia (low blood sugar). This would cause a patient or health care professional not to take the appropriate steps to bring the blood sugar into a normal range. A falsely elevated blood glucose reading could cause a patient to get more insulin than needed. Both of these situations can lead to life-threatening events, including loss of consciousness, coma, permanent neurological damage or death.

Additional considerations for patients who use **EXTRANEAL** (icodextrin) PD solution:

1. Discontinuing **EXTRANEAL** (icodextrin) PD solution use will not immediately address the risk for the potential interference with glucose monitors. Falsely elevated glucose levels may result up to two weeks following cessation of **EXTRANEAL** (icodextrin).
2. To determine what type of method is used for monitoring glucose levels, review the labeling for BOTH the glucose monitor and the test strips used. If in doubt, contact the manufacturer of the glucose monitors and test strips to determine the method that is used.
3. If your hospital uses electronic medical records, the above information describing the potential for interference with blood glucose monitors or test strips needs to be entered in a suitable field that is readily apparent to all users.

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** (icodextrin) PD solution, please contact your Baxter Renal Representative.

Sincerely,

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

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EXTRANEAL (icodextrin) Peritoneal Dialysis (PD) Solution

Dangerous Drug-Device Interaction
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Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

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 HelpLine 1-888-RENAL-HELP or visit www.glucosesafety.com.

EXTRANEAL PD solution is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with pre-existing severe lactic acidosis, and in patients with glycogen storage disease.

EXTRANEAL PD solution is intended for intraperitoneal administration only. Not for intravenous injection.

Rarely, serious hypersensitivity reactions to EXTRANEAL have been reported, such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme, and leukocytoclastic vasculitis. If a serious reaction is suspected, discontinue EXTRANEAL and institute appropriate treatment as clinically indicated.

Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment.

A patient's volume status should be carefully monitored to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock. An accurate fluid balance record must be kept and the patient's body weight monitored.

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. Additional adverse reactions have been reported in the post-marketing setting and are detailed in the full prescribing information.

General Peritoneal Dialysis-Related
Encapsulating Peritoneal Sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including EXTRANEAL PD solution. Infrequent but fatal outcomes have been reported.

Aseptic technique should be used throughout the peritoneal dialysis procedure to reduce the possibility of infection, such as peritonitis.

Fluid status, hematologic indices, blood chemistry, and electrolyte concentrations, including calcium, potassium, sodium, magnesium and bicarbonate, should be monitored periodically. Abnormalities in any of these parameters should be treated promptly under the care of a physician.

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is to drain the peritoneal dialysis solution from the peritoneal cavity.

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

Please see full prescribing information.

Attention Hospital Pharmacy

WARNING

Potential For Incorrect Blood Glucose Reading

November 2010

Dear Director of 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.

Patients using EXTRANEAL (icodextrin) peritoneal dialysis solution may have incorrect blood glucose results when using particular blood glucose monitors and test strips.

ONLY use glucose monitors and test strips that are glucose-specific. Some glucose monitors are not glucose-specific and cannot tell the difference between glucose and other sugars in the blood (e.g., maltose, a metabolite of icodextrin). Use laboratory-based methods, if available or a glucose-specific monitor and test strips. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used. Visit www.glucosesafety.com for additional information including a glucose monitor compatibility list.

The term "glucose-specific" applies to monitors or test strips that are not affected by the presence of maltose or certain other sugars. Because **EXTRANEAL** (icodextrin) PD solution results in elevated blood levels of maltose, only glucose-specific monitors and test strips should be used.

DO NOT use glucose monitors or test strips that utilize glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO) methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method should not be used. Use of these methods may result in falsely elevated blood glucose readings in patients using **EXTRANEAL** (icodextrin) due to maltose interference. A blood glucose reading with these monitors that appears to be within the normal range in a patient on **EXTRANEAL** (icodextrin) may mask true hypoglycemia (low blood sugar). This would cause a patient or health care professional not to take the appropriate steps to bring the blood sugar into a normal range. A falsely elevated blood glucose reading could cause a patient to get more insulin than needed. Both of these situations can lead to life-threatening events, including loss of consciousness, coma, permanent neurological damage or death.

Additional considerations for patients who use **EXTRANEAL** (icodextrin) PD solution:

1. Discontinuing **EXTRANEAL** (icodextrin) PD solution use will not immediately address the risk for the potential interference with glucose monitors. Falsely elevated glucose levels may result up to two weeks following cessation of **EXTRANEAL** (icodextrin).
2. To determine what type of method is used for monitoring glucose levels, review the labeling for BOTH the glucose monitor and the test strips used. If in doubt, contact the manufacturer of the glucose monitors and test strips to determine the method that is used.
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Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

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Fluid status, hematologic indices, blood chemistry, and electrolyte concentrations, including calcium, potassium, sodium, magnesium and bicarbonate, should be monitored periodically. Abnormalities in any of these parameters should be treated promptly under the care of a physician.

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is to drain the peritoneal dialysis solution from the peritoneal cavity.

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

Please see full prescribing information.

Attention Laboratory Services
WARNING
Potential For Incorrect Blood Glucose Reading

November 2010

Dear Director of 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.

Patients using EXTRANEAL (icodextrin) peritoneal dialysis solution may have incorrect blood glucose results when using particular blood glucose monitors and test strips.

ONLY use glucose monitors and test strips that are glucose-specific. Some glucose monitors are not glucose-specific and cannot tell the difference between glucose and other sugars in the blood (e.g., maltose, a metabolite of icodextrin). Use laboratory-based methods, if available or a glucose-specific monitor and test strips. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used. Visit www.glucosesafety.com for additional information including a glucose monitor compatibility list.

The term "glucose-specific" applies to monitors or test strips that are not affected by the presence of maltose or certain other sugars. Because **EXTRANEAL** (icodextrin) PD solution results in elevated blood levels of maltose, only glucose-specific monitors and test strips should be used.

DO NOT use glucose monitors or test strips that utilize glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO) methods. In addition, some but not all monitors or test strips that utilize a glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) method must not be used. Use of these methods may result in falsely elevated blood glucose readings in patients using **EXTRANEAL** (icodextrin) due to maltose interference. A blood glucose reading with these monitors that appears to be within the normal range in a patient on **EXTRANEAL** (icodextrin) may mask true hypoglycemia (low blood sugar). This would cause a patient or health care professional not to take the appropriate steps to bring the blood sugar into a normal range. A falsely elevated blood glucose reading could cause a patient to get more insulin than needed. Both of these situations can lead to life-threatening events, including loss of consciousness, coma, permanent neurological damage or death.

Additional considerations for patients who use **EXTRANEAL** (icodextrin) PD solution:

1. Discontinuing **EXTRANEAL** (icodextrin) PD solution use will not immediately address the risk for the potential interference with glucose monitors. Falsely elevated glucose levels may result up to two weeks following cessation of **EXTRANEAL** (icodextrin).
2. To determine what type of method is used for monitoring glucose levels, review the labeling for BOTH the glucose monitor and the test strips used. If in doubt, contact the manufacturer of the glucose monitors and test strips to determine the method that is used.
3. If your hospital uses electronic medical records, the above information describing the potential for interference with blood glucose monitors or test strips needs to be entered in a suitable field that is readily apparent to all users.

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** (icodextrin) PD solution, please contact your Baxter Renal Representative.

Sincerely,

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

Please see Important Risk Information on reverse side and enclosed Full Prescribing Information.

This letter is part of an FDA approved REMS

IMPORTANT RISK INFORMATION
EXTRANEAL (icodextrin) Peritoneal Dialysis (PD) Solution

Dangerous 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, see **PRECAUTIONS/Drug/Laboratory Test Interactions**). 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.

Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using EXTRANEAL (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with EXTRANEAL (icodextrin).

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

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 HelpLine 1-888-RENAL-HELP or visit www.glucosesafety.com.

EXTRANEAL PD solution is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with pre-existing severe lactic acidosis, and in patients with glycogen storage disease.

EXTRANEAL PD solution is intended for intraperitoneal administration only. Not for intravenous injection.

Rarely, serious hypersensitivity reactions to EXTRANEAL have been reported, such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme, and leukocytoclastic vasculitis. If a serious reaction is suspected, discontinue EXTRANEAL and institute appropriate treatment as clinically indicated.

Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment.

A patient's volume status should be carefully monitored to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock. An accurate fluid balance record must be kept and the patient's body weight monitored.

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. Additional adverse reactions have been reported in the post-marketing setting and are detailed in the full prescribing information.

General Peritoneal Dialysis-Related
Encapsulating Peritoneal Sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including EXTRANEAL PD solution. Infrequent but fatal outcomes have been reported.

Aseptic technique should be used throughout the peritoneal dialysis procedure to reduce the possibility of infection, such as peritonitis.

Fluid status, hematologic indices, blood chemistry, and electrolyte concentrations, including calcium, potassium, sodium, magnesium and bicarbonate, should be monitored periodically. Abnormalities in any of these parameters should be treated promptly under the care of a physician.

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is to drain the peritoneal dialysis solution from the peritoneal cavity.

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure.

Please see full prescribing information.

Attention Hospital Admissions Staff

WARNING

Potential For Incorrect Blood Glucose Reading

November 2010

Dear Hospital Admissions Staff,

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Patients using EXTRANEAL (icodextrin) peritoneal dialysis solution may have incorrect blood glucose results when using particular blood glucose monitors and test strips.

ONLY use glucose monitors and test strips that are glucose-specific. Some glucose monitors are not glucose-specific and cannot tell the difference between glucose and other sugars in the blood (e.g., maltose, a metabolite of icodextrin). Use laboratory-based methods, if available or a glucose-specific monitor and test strips. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used. Visit www.glucosesafety.com for additional information including a glucose monitor compatibility list.

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Additional considerations for patients who use **EXTRANEAL** (icodextrin) PD solution:

1. Discontinuing **EXTRANEAL** (icodextrin) PD solution use will not immediately address the risk for the potential interference with glucose monitors. Falsely elevated glucose levels may result up to two weeks following cessation of **EXTRANEAL** (icodextrin).
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