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extraneal

EXTRANEAL (icodextrin)

Peritoneal Dialysis Solution:

A Patient Training Tool

pd

What You Should Know About EXTRANEAL (icodextrin) Peritoneal Dialysis Solution

Your doctor has prescribed **EXTRANEAL** (icodextrin) Peritoneal Dialysis Solution as one of your solutions for peritoneal dialysis (PD).

- It's important to do your dialysis as your doctor has prescribed.
- **EXTRANEAL** is indicated for use as an osmotic agent for long dwell, up to 12 hours, in continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD), where it can be used for 14 and up to 16 hours.
- It's equally important to do your PD exchanges just as you were taught, every time.
- 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.
- **If you have insulin-dependent diabetes, pay attention to your insulin dose. See important safety information on page 4.**
- 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** – don't worry. The color appears when **EXTRANEAL** mixes with leftover povidone-iodine in the **MiniCap** Disconnect Cap.
- Store **EXTRANEAL** at room temperature (15°-25°C)
  - Until you use it, keep **EXTRANEAL** in its moisture barrier overpouch in its carton.
  - Avoid high heat (40°C) and do not store below 4°C.

Always keep some 1.5% dextrose solution at home. Why?

- Using both 4.25% dextrose solution and **EXTRANEAL** 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.
- Talk to your PD nurse or dialysis doctor about adding any medications to **EXTRANEAL.**

What To Watch For

You may experience certain side effects while using **EXTRANEAL**. It's important to be aware of and report any symptoms you may have. Here are some guidelines:

Rash is the most common side effect of **EXTRANEAL**. It usually appears during the first 3 weeks of treatment and goes away when treatment stops.

Refer to the Product Monograph for a broader list of side effects. If you experience any side effects while taking **EXTRANEAL**, contact your dialysis doctor or nurse.

For patients using the **HomeChoice** Automated PD System and the last fill option, the cycler should be programmed to "dextrose different" and to the volume of **EXTRANEAL** to be infused. The **EXTRANEAL** bag should be attached to the line with the blue clamp (last fill line).

Important Safety Information for EXTRANEAL (icodextrin) Patients Who Measure Blood Sugar (Glucose) Levels

Icodextrin or its by-products, such as maltose, may cause some types of glucose monitors and/or test strips to give a **false high glucose reading**.

- To avoid interference by maltose or other metabolites of **EXTRANEAL** (icodextrin), **ONLY use glucose monitors and test strips that are glucose-specific. These methods are common in clinical laboratories. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used.**
- 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 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. Falsely elevated blood glucose readings may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia, leading to life-threatening events.

- A false high glucose reading could cause you or a clinician to give you more insulin than you need.
- A false high glucose reading may mask a very low actual glucose reading and cause you to delay in correcting the low blood sugar.
- Both of these situations can cause loss of consciousness, coma, neurological damage and death.

Please visit www.glucosesafety.com for Product Monograph and further related information on **EXTRANEAL.**

What To Do

- You or your PD nurse must confirm that your glucose monitor(s) and test strip(s) will provide an accurate reading when using **EXTRANEAL**.
- You must notify your PD nurse and dialysis doctor before you change your home glucose monitor(s) or test strip(s).
- It is important to regularly check the test method of your glucose monitor(s) and test strip(s) with **EXTRANEAL**. Should the manufacturer that makes your glucose monitor or test strips change its methods of glucose measurement, be sure to contact your PD nurse or dialysis doctor to let them know. They can help you make adjustments if necessary.
- Be sure to 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 glucose readings.

If you have insulin-dependent diabetes, pay attention to your insulin dose and always monitor your blood sugar levels as directed by your dialysis doctor. Here are a few guidelines to follow:

- See important safety information about glucose monitors and test strips on page 3 for additional cautionary measures.
- Be sure to check your blood sugar levels regularly.
- You may need to alter your insulin dose so please discuss with your PD nurse and dialysis doctor.

What to do if you see health care providers other than those at your PD Clinic:

- Tell the doctors and nurses that you are using **EXTRANEAL** (icodextrin), and that some glucose monitors and test strips may give a false high glucose reading.

- Take the **EXTRANEAL** admission envelope with you and give it to the doctor or nurse treating you. This envelope has additional information related to glucose monitors for doctors and nurses.

- Even if you stop using **EXTRANEAL**, this will not resolve the potential for interference with glucose monitors or test strips. Your blood will have increased levels of icodextrin and maltose for up to two weeks after stopping the use of **EXTRANEAL**.

Included is a **necklace** that is designed to alert clinicians about the potential for incorrect blood glucose measurements. You should wear it to alert clinicians in an emergency.

A **wallet card** is included here. Present your wallet card, which explains the risks of how maltose may interfere with some glucose monitors.

WARNING AND PRECAUTION
Potential for Incorrect Blood Glucose Reading

To avoid interference by maltose or other metabolites of **EXTRANEAL** (icodextrin), **ONLY use glucose monitors and test strips that are glucose-specific. These methods are common in clinical laboratories. Contact the manufacturer of the glucose monitors and test strips to determine the method that is used.**

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 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. Falsely elevated blood glucose readings may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia, leading to life-threatening events.

For further information, call 1-866-447-5076.
For more information on **EXTRANEAL** and additional glucose monitor information, including a glucose monitor compatibility list, visit www.glucosesafety.com

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MISE EN GARDE ET PRÉCAUTION
Risque de lecture incorrecte de la glycémie

Pour éviter une interférence du maltose ou d'autres métabolites d'**EXTRANEAL** (icodextrine), employez **UNIQUEMENT des glucomètres et des bandelettes d'analyse faisant appel à des méthodes spécifiques au glucose. De telles méthodes sont courantes dans les laboratoires cliniques. Communiquer avec le fabricant du glucomètre et des bandelettes d'analyse pour connaître la méthode utilisée.**

NE PAS employer de glucomètres ni de bandelettes d'analyse utilisant la glucose-déshydrogénase pyrroloquinoléine quinone (GDH-PQQ) ou la glucose-dye-oxydoréductase. En outre, il convient de ne pas utiliser certains glucomètres ou bandelettes d'analyse qui utilisent la glucose déshydrogénase avec flavine-adénine dinucléotide (GDH-FAD). L'utilisation de ces méthodes pourrait entraîner une lecture de glycémie faussement élevée causée par une interférence du maltose chez les patients recevant **EXTRANEAL** (icodextrine). Les mesures de glucose faussement élevées peuvent masquer une hypoglycémie réelle ou mener par erreur à un diagnostic d'hyperglycémie, ce qui peut avoir des effets mettant la vie en danger.

Pour plus d'information, appeler le 1-866-447-5076. Pour obtenir de plus amples renseignements sur **EXTRANEAL** et de l'information complémentaire sur les glucomètres, notamment la liste de compatibilité des glucomètres, veuillez visiter le site www.glucosesafety.com

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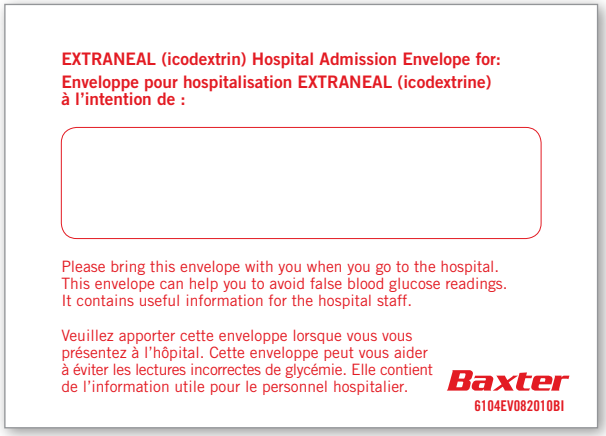
EXTRANEAL (icodextrin) Admission Envelope

Because you are on **EXTRANEAL**, you have received an **EXTRANEAL admission envelope**. The envelope contains an important **information sheet** regarding blood glucose levels for your health care team.



EXTRANEAL (icodextrin) Hospital Admission Envelope for:
Enveloppe pour hospitalisation EXTRANEAL (icodextrine) à l'intention de :

Please bring this envelope with you when you go to the hospital. This envelope can help you to avoid false blood glucose readings. It contains useful information for the hospital staff.

Veuillez apporter cette enveloppe lorsque vous vous présentez à l'hôpital. Cette enveloppe peut vous aider à éviter les lectures incorrectes de glycémie. Elle contient de l'information utile pour le personnel hospitalier.

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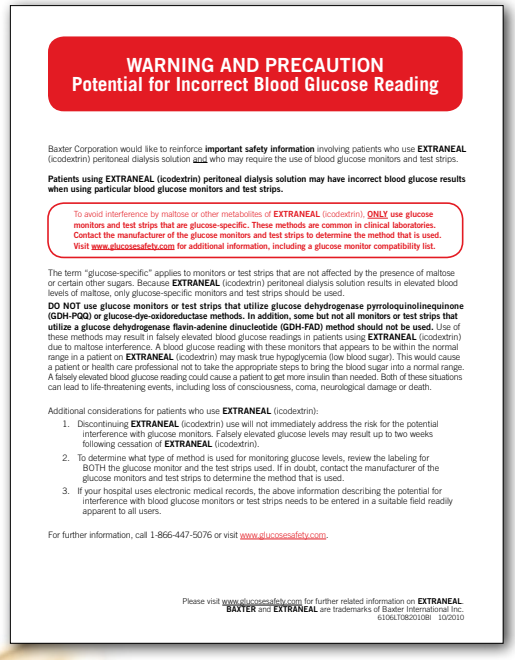
Admission Envelope



WARNING AND PRECAUTION
Potential for Incorrect Blood Glucose Reading

Baxter Corporation would like to reinforce **important safety information** involving patients who use **EXTRANEAL** (icodextrin) peritoneal dialysis 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.

To avoid interference by maltose or other metabolites of **EXTRANEAL** (icodextrin), **ONLY use glucose monitors and test strips that are glucose-specific. These methods are common in clinical laboratories. 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) peritoneal dialysis 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 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, neurological damage or death.

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

1. Discontinuing **EXTRANEAL** (icodextrin) 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 readily apparent to all users.

For further information, call 1-866-447-5076 or visit www.glucosesafety.com.

Please visit www.glucosesafety.com for further related information on **EXTRANEAL**.
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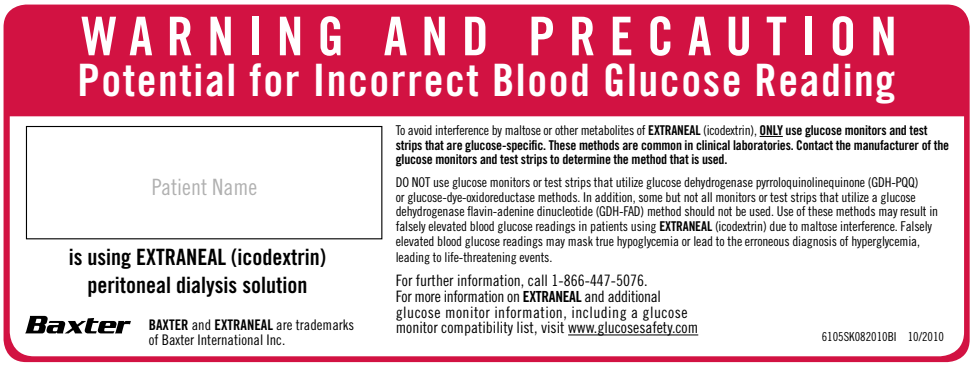
Information Sheet

Please visit www.glucosesafety.com for Product Monograph and further related information on **EXTRANEAL**.

There is also a patient **chart sticker** which your clinician may want to use to remind them about your history and can be attached to your medical chart. Your PD nurse will also show you a sample of the envelope and explain all of the components that are included. Some patients find it convenient to keep this kit with their medical travel supplies.



Patient Chart Sticker

Whenever you go to the hospital, be sure to bring your **EXTRANEAL** admission envelope along with you.

- It's important to take the admission envelope with you when you go to the hospital because of this essential information regarding **EXTRANEAL** and measuring blood glucose levels. Simply give it to the nurse or physician who is seeing you.

If you require a replacement envelope, please order one through your Baxter Customer Care Representative (CCR) Team at 1-866-968-7477.

NOTES

Please visit www.glucosesafety.com for Product Monograph and further related information on **EXTRANEAL.**

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For more information, contact your Renal Team.

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