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EXTRANEAL (icodextrin)

Peritoneal Dialysis Solution

EXTRANEAL (icodextrin)

Peritoneal Dialysis Solution:

A Guide for the PD Nurse

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Information for the PD Nurse About EXTRANEAL (icodextrin) Peritoneal Dialysis Solution

INDICATIONS AND CONTRAINDICATIONS

- **EXTRANEAL** is indicated for use as an osmotic agent for the 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.
- **EXTRANEAL** is contraindicated for use in patients with:
  - acute renal failure
  - an allergy to starch-based polymers and/or icodextrin
  - maltose or isomaltose intolerance
  - glycogen storage disease
  - pre-existing severe lactic acidosis
- The product is also contraindicated in patients with a history of abdominal surgery in the month preceding commencement of therapy, patients with abdominal fistulae, tumors, open wounds, herniae or other conditions which compromise the integrity of the abdominal wall, abdominal surface or intra-abdominal cavity in common with other peritoneal dialysis fluids. In patients with impaired respiratory function or potassium deficiency, peritoneal dialysis may also be contraindicated.
- **EXTRANEAL** is not recommended for use in children.

USE IN PREGNANCY & LACTATION

- No data from animal studies on the effects of **EXTRANEAL** on reproduction or lactation are available and therefore, **EXTRANEAL** solution should not be used during pregnancy or lactation. Women of childbearing potential should be treated with **EXTRANEAL** solution only when adequate contraceptive precautions have been taken. Potential effects on male and female fertility are unknown.

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

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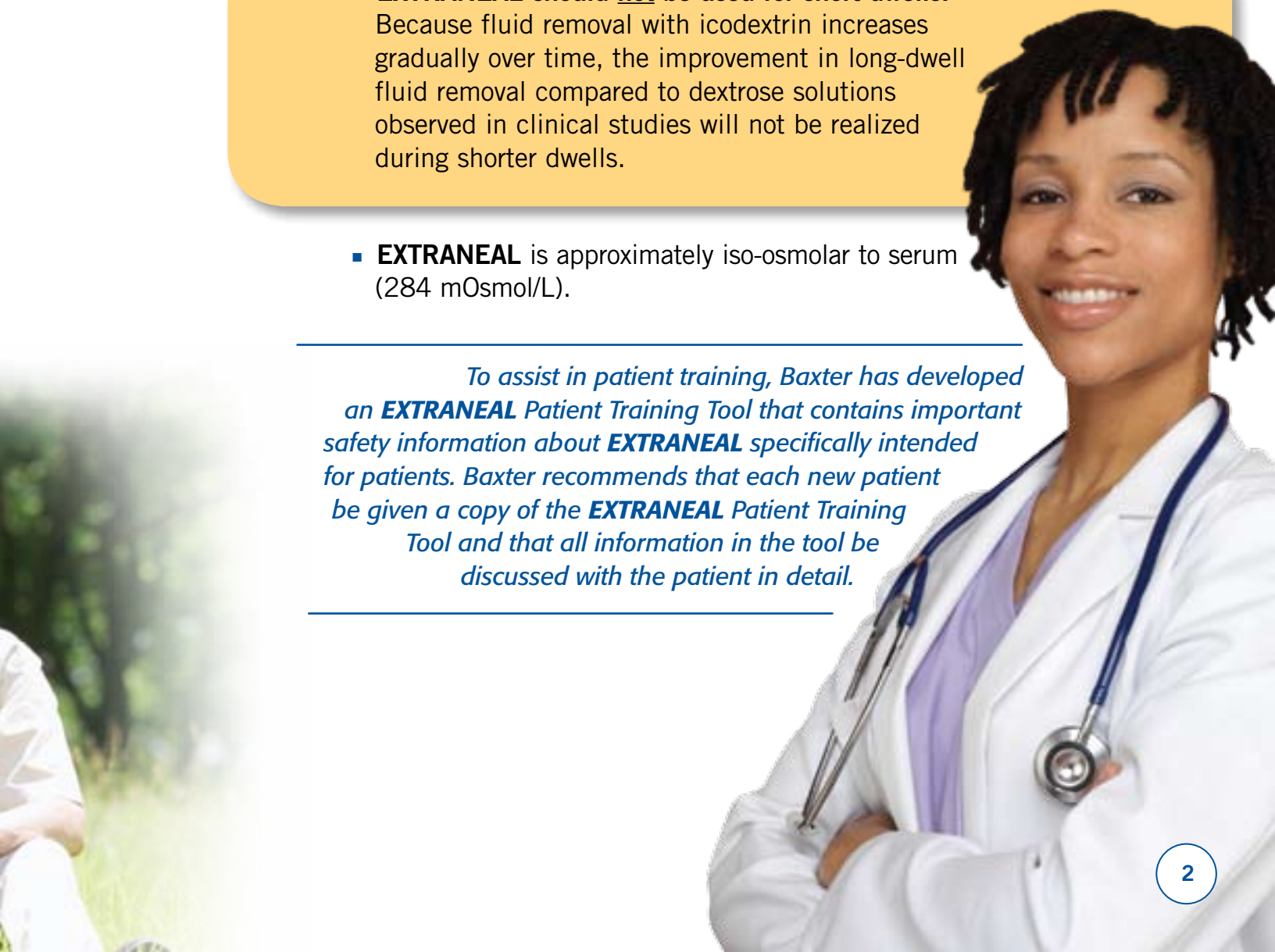
DESCRIPTION AND USAGE

- Icodextrin is a starch-derived glucose polymer that removes fluid through the process of colloid osmosis; due to their large size, icodextrin molecules induce movement of water through the small pores of the peritoneal membrane.

- **EXTRANEAL should not be used for short dwells.** Because fluid removal with icodextrin increases gradually over time, the improvement in long-dwell fluid removal compared to dextrose solutions observed in clinical studies will not be realized during shorter dwells.

- **EXTRANEAL** is approximately iso-osmolar to serum (284 mOsmol/L).

*To assist in patient training, Baxter has developed an **EXTRANEAL** Patient Training Tool that contains important safety information about **EXTRANEAL** specifically intended for patients. Baxter recommends that each new patient be given a copy of the **EXTRANEAL** Patient Training Tool and that all information in the tool be discussed with the patient in detail.*



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PRESCRIBING CONSIDERATIONS

- A patient's volume status should be carefully monitored to avoid hypervolemia or hypovolemia.
- A patient using **EXTRANEAL** may become dehydrated if 4.25% dextrose is used for one or more of the other exchanges. Patients should always have some 1.5% dextrose available.
- Patients with insulin-dependent diabetes may require an adjustment of their insulin dosage following initiation of treatment with **EXTRANEAL**. Appropriate monitoring of blood glucose should be performed and insulin dosage adjusted if needed **(See important information about glucose monitors and test strips on page 5).**
- **EXTRANEAL** may affect certain laboratory test results.
    - Serum sodium and chloride levels may be slightly lower.
    - Serum alkaline phosphatase level may be higher.
    - Serum amylase levels may appear to be lower due to interference of **EXTRANEAL** with serum amylase assays resulting in inaccurately low values. This interference should be taken into account when evaluating serum amylase levels for diagnosis or monitoring of pancreatitis in patients using **EXTRANEAL.**

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.

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- The following medications have shown no evidence of incompatibility with **EXTRANEAL**: insulin, ceftazidime, vancomycin, gentamicin, cefazolin, amphotericin, ampicillin/flucloxacillin.
- **EXTRANEAL** is not available in a low calcium (1.25 mmol/L) formulation. **EXTRANEAL** always has 1.75 mmol/L of calcium.

- 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).

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Important Information Regarding the Use of Glucose Monitors and Test Strips

Patients Receiving EXTRANEAL (icodextrin) May Have Incorrect Blood Glucose Results When Using Particular Blood Glucose Monitoring Systems.

- 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.**
- **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.

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Recommendations for patient training and follow-up regarding glucose monitors and test strips:

- Use the **EXTRANEAL** (icodextrin) Patient Training Tool to review the information about glucose monitor and test strip interference, particularly the need to alert health care providers outside the dialysis unit (e.g., emergency room, hospital, outpatient clinic, physician offices).
- Train the patient and all caregivers on the importance of using only certain monitors and test strips and about the potential consequences if these guidelines are not followed. Recommend that any emergency contacts also be made aware of this information.
- Verify the type of glucose monitor and test strips used by the patient; call or instruct the patient to call the manufacturers to verify that the monitor and/or test strips measure only glucose. Monitors and test strips that are subject to maltose interference must not be used.

- Your PD unit has received a Demonstration Kit, which contains a sample of all the items included in the **EXTRANEAL** Patient Kit. Review the contents of the kit with the patient.
- Assist the patient in completing the information on the Wallet Card included in the **EXTRANEAL** Patient Training Tool.
- To reorder the **EXTRANEAL** Demonstration Kit and the Patient Kit, please contact your Baxter Renal Specialist.

Possible Reasons for an Unexpectedly Low Ultrafiltration (UF) Response to EXTRANEAL (icodextrin)

Several factors can contribute to low long-dwell net UF, including a change in fluid intake, catheter flow interference, incorrect programming of the last fill on the **HomeChoice** Automated PD System (not selecting "dextrose different"), and a need for a modification to the dialysis prescription. It is also important to determine whether the patient has adequate peritoneal membrane function and can still perform peritoneal dialysis. Once these factors have been ruled out, the following possibilities related to **EXTRANEAL** should be considered:

- **PATIENT-RELATED ISSUES**
  - Variable response: The UF volume produced by **EXTRANEAL** as reported in controlled clinical trials represents the average UF response; the UF volume of individual patients may have been smaller or larger.
  - Duration of dwell: The mechanism of action of icodextrin as a colloid osmotic agent results in a gradual, sustained increase in UF over a period of up to 12 hours in CAPD or up to 16 hours in APD. Use of **EXTRANEAL** for short dwells may result in lower-than-expected net UF.
  - Lymphatic absorption: A small number of patients have enhanced lymphatic absorption and therefore will more rapidly remove icodextrin from the peritoneal cavity. More rapid removal of icodextrin results in less UF during the long dwell. Patients with high lymphatic absorption can be identified using the **Peritoneal Equilibration Test (PET)** and **PD ADEQUEST**. For these patients, consideration should be given to shortening the long dwell.

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- **TECHNICAL ISSUES FOR PATIENTS USING CYCLER THERAPY**
  - Dialysis solution bags contain a slight overfill volume, but due to the functionality and safety mechanisms of **HomeChoice** cycler, less than the programmed volume may be delivered to the patient for the last fill. The actual last fill volume can be viewed in the therapy log. In addition, actual last fill and UF volumes can be readily seen when using **RenalSoft** software. If the last fill volume is less than 75% of the programmed last fill, the **HomeChoice** cycler will alarm.
    - **REASONS WHY THE HOMECHOICE CYCLER DELIVERS LESS THAN THE PROGRAMMED FILL VOLUME:**
      - Flush: At the time of set-up, approximately 100 mL of dialysis solution is flushed from each bag connected to the **HomeChoice** cycler tubing and delivered to the drain.
      - Residual volume: When solution is transferred from the last bag to the heater bag or from the heater bag to the patient, some residual solution will remain in the bag and tubing, depleting the volume available for last fill.
      - Detecting and resolving flow restrictions: If any flow restrictions are detected during the last drain, **EXTRANEAL** will be delivered to the patient in an attempt to resolve the flow restriction. This solution will then be sent to the drain.

Performing a 24-hour Collection With EXTRANEAL (icodextrin) in Patients on Automated Peritoneal Dialysis (APD)

When a 24-hour collection is being done for an APD patient using **EXTRANEAL**, consider the following two possible situations:

1. The patient uses the entire amount of PD solution for overnight therapy before **EXTRANEAL** is infused. For example, the prescription is for four 2.5-L exchanges of dextrose plus a last bag fill of **EXTRANEAL**, and the patient uses two 5-L bags of dextrose and one 2-L bag of **EXTRANEAL**. For this situation, standard collection procedures should be followed.
2. The patient does not use the entire amount of PD solution for overnight therapy before **EXTRANEAL** is infused. For example, the prescription is for four 2-L exchanges of dextrose plus a last bag fill of **EXTRANEAL**, and the patient uses two 5-L bags of dextrose and one 2-L bag of **EXTRANEAL**. The 2-L excess of dextrose solution will be "purged" into the drain bag, which will dilute the solution collected from the patient. For this situation, the cycler must be programmed differently (see below) and **EXTRANEAL** should be infused manually using a Baxter CAPD solution delivery system.
    - Program the cycler for no last fill ("last fill = 0 mL").
    - Reprogram the "total therapy volume" to be only the amount of dialysate used for night cycles.
    - Do not connect the **EXTRANEAL** solution bag to the cycler set.
    - At the end of cycler therapy, instruct the patient to perform manual exchange with **EXTRANEAL.**
    - After the 24-hour collection is completed, reprogram the cycler to the original setup.

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NOTES

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For more information, contact your Renal Team.

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6103BR082010EN 10/2010