

PATIENT INFORMATION
EXTRANEAL
(generic name - icodextrin)

Read this information carefully before you begin treatment with EXTRANEAL (X-tra-neel). As there may be new information in the future, read the information you get whenever you get a new delivery of EXTRANEAL. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about EXTRANEAL, ask your doctor. Only your doctor can determine if EXTRANEAL is right for you.

What is EXTRANEAL?

EXTRANEAL is a sterile peritoneal dialysis solution. EXTRANEAL contains icodextrin, which is made from cornstarch. It draws fluid and wastes from your bloodstream into your peritoneal cavity (the space inside your abdomen). The fluids and wastes are removed from your body when the EXTRANEAL solution is drained.

EXTRANEAL is used for the long dwell exchange (8- to 16- hours) in peritoneal dialysis. The long dwell is the exchange that lasts 8 hours or more (the nighttime exchange if you are on continuous ambulatory peritoneal dialysis (CAPD) and the daytime exchange if you are using a cycler). You should use EXTRANEAL only for this exchange, and not more than 1 exchange in 24 hours.

Who should not use EXTRANEAL?

Do not use EXTRANEAL:

- If a doctor has ever told you that you have a glycogen storage disease
- If you are allergic to cornstarch or have had an allergic reaction to icodextrin

Tell your doctor about all the medicines you take, including insulin and blood pressure medicines. Your dose of these medicines may need to be changed when you use EXTRANEAL.

If you monitor your blood glucose, you must use a glucose specific monitor and test strips. If your glucose monitor or test strips use a glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase method, using EXTRANEAL may cause a falsely high glucose reading or may mask a very low actual glucose reading. A false high blood glucose reading could cause you to give more insulin than you need. Getting more insulin than you need can cause a serious reaction including loss of consciousness, coma, neurological damage and death. If you have true low blood sugar but are using a monitor that is not specific, you may inadvertently delay taking appropriate measures to correct the low blood sugar. YOU OR YOUR NURSE OR DOCTOR SHOULD CONTACT THE MANUFACTURER(S) OF THE MONITOR AND TEST STRIPS TO MAKE SURE THAT EXTRANEAL, ICODEXTRIN OR MALTOSE WILL NOT INTERFERE WITH THE TEST RESULTS.

If you are ever hospitalized or admitted to the emergency room, notify the hospital staff that you are using EXTRANEAL and that icodextrin and maltose may give a false high glucose reading with some types of glucose monitors or test strips.

Tell your doctor if you:

- Have a condition that restricts normal nutrition (you do not eat well)
- Have a lung or breathing problem
- Have low potassium levels in your blood
- Have high calcium levels in your blood
- Are pregnant or plan to become pregnant. EXTRANEAL may not be right for you.
- Are breastfeeding
- Use cardiac glycosides, such as digoxin. Your doctor may need to monitor your blood levels of calcium, potassium and magnesium.

Tell your doctor if you have had abdominal (stomach area):

- Surgery in the past 30 days
- Tumors
- Open wounds
- Hernia

Tell your doctor about any other conditions you have that may affect the wall of your abdomen, inside or outside of your abdomen.

How should I use EXTRANEAL?

- EXTRANEAL is for your long dwell (8- to 16- hours) peritoneal dialysis exchange. Use EXTRANEAL for this exchange only, and not more than 1 exchange in 24 hours.
- To do your EXTRANEAL exchange, you should follow the steps learned in your peritoneal dialysis training. It is very important that you follow the steps shown to you in your peritoneal dialysis training. All surfaces and connecting parts must be clean to avoid serious infection. If you need more help or have any questions you should contact your dialysis center or doctor.
- Before use, always check to make sure the bags are not leaking and the date for using the solution (expiration date) has not passed. Do not use EXTRANEAL after the expiration date shown on the carton and product label.
- Make sure that the solution is clear and does not contain particles. Do not use bags that are cloudy, leaking or that contain particles.
- To make using EXTRANEAL more comfortable, you can warm it in the overpouch to 98.6°F/37°C before use. This should only be done using dry heat, such as a heating pad.
- To avoid increased risk of infection, do not place EXTRANEAL in water to heat the bags.
- Do not microwave EXTRANEAL. You can damage the solution if it gets hotter than 104°F (40°C).
- If you use a manual method of peritoneal dialysis (CAPD), EXTRANEAL should be infused over 10 to 20 minutes at a rate that is comfortable for you. When draining the

fluid after the dwell, always check the drained fluid for cloudiness or fibrin. Fibrin looks like clumps or stringy material in the drained solution. Cloudy drained fluid or fibrin may mean you have an infection. Call your doctor if your drained fluid is cloudy or contains fibrin.

- Carefully monitor your fluid balance. Keep an accurate fluid record. Carefully monitor your body weight to avoid too much or too little fluid in your body (over- or under-hydration) which may have serious effects, such as heart failure and shock.
- Talk to your doctor before adding any other medicines to EXTRANEAL.

What are the possible side effects of 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. Rash is more common in women.

Other side effects of EXTRANEAL

Some patients using EXTRANEAL have the following side effects:

Peritonitis (an infection in the peritoneal cavity), high blood pressure, cold, headache, abdominal pain, cough, flu-like symptoms, nausea, swelling, chest pain, upset stomach, and high blood sugar.

Some of these side effects like peritonitis are common in people on peritoneal dialysis. Report any symptoms of peritonitis (pain, redness, fever, cloudy drained fluid) to your doctor right away.

These are not all of the possible side effects of EXTRANEAL. For a complete list, ask your doctor or dialysis center.

How should I store EXTRANEAL?

Store at room temperature 68-77°F (20-25°C). Store in the moisture barrier overpouch in the carton until ready to use.

Avoid high heat (104°F/40°C).

Protect EXTRANEAL from freezing.

This leaflet summarizes the most important information about EXTRANEAL. If you would like more information, talk with your doctor. You can ask your dialysis center or doctor for information about EXTRANEAL that is written for health professionals.

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