

EXTRANEAL (ICODEXTRIN 7.5%)

Icodextrin

Consumer Medicine Information

Blood glucose management with Extraneal must be done with a glucose-specific method to avoid interference resulting in unrecognised hypoglycemia. If non-specific glucose test methods (GDH-PQQ) are used, loss of consciousness, neurological damage and death may occur.

WHAT IS IN THIS LEAFLET

This leaflet answers some more common questions about Extraneal. It does not contain all of the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Extraneal against the benefit they expect it will have for you.

It does not take the place of talking to your doctor.

If you have any concerns about taking the medicine, ask your doctor or renal nurse.

Keep this leaflet with the medicine, as you may need to read it again.

WHAT EXTRANEAL IS USED FOR

Extraneal is used as a replacement for a single glucose exchange (e.g. Dianeal product), as part of a Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) regimen for chronic renal failure.

BEFORE THE USE OF EXTRANEAL FORMULA

Do not use Extraneal if:

You have a known allergy to any of the ingredients listed at the end of this leaflet or to starch.

You have a glycogen storage disease.

Additionally tell your doctor if you have recently had surgery on your stomach or if you have any other stomach complaints.

Precautions:

Blood glucose measurement must be done with a glucose-specific method to prevent maltose interference with test results. Since falsely elevated glucose levels have been observed with blood glucose monitoring devices and test strips that use glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ)-based methods, GDH PQQ-based methods should not be used to measure glucose levels in patients administered EXTRANEAL.

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

- 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

Use during pregnancy or breastfeeding

Extraneal is not recommended if you are pregnant or breastfeeding. Your doctor should make sure that you are not pregnant before using Extraneal. If you are of child bearing age, you must use a reliable method of birth control while using Extraneal.

Use on the elderly

Extraneal has not been shown to cause different side effects or problems in older people than it does in younger adults.

Paediatric use

Extraneal is not recommended in children less than 18 years.

Potential effects of this product on the ability to drive vehicles or operate machinery

Use of this product will not affect your ability to drive or operate machinery.

You will not however be able to drive nor operate machinery whilst you are administering this product.

Interaction with other medicines

Treatment with cardiac glycosides may be affected if taken whilst using Extraneal. Your doctor will carefully monitor your blood to determine if dialysis is affecting the level of drugs in your system.

Blood Glucose Testing

It should be noted that Extraneal may interfere with the measurement of blood glucose by certain testing kits (including the test strips). A falsely high glucose might be found. If you need to test your blood glucose, your physician will advise you on which kit to use.

Special Warnings:

There have been reported deaths associated with hypoglycaemia and hypoglycaemic incidents that have resulted in permanent neurological damage. This is a result of falsely high blood glucose readings due to the interaction between Icodextrin and its by-products and glucometers that use pyrroloquinolinequinone (GDH-PQQ) for measuring blood glucose. Blood glucose measurement in patients receiving EXTRANEAL must be done with a glucose specific method (monitor and test strips) to avoid interference by maltose, released from EXTRANEAL. Glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ)-based methods must not be used. The manufacturer(s) of the monitor and test strips should be contacted to determine if Icodextrin or maltose causes interference or falsely elevated glucose results.

Extraneal should not be used if you have been diagnosed with acute renal failure.

How to use Extraneal Formula properly

How much to use:

Your doctor will decide the dosage of Extraneal. For adult patients of normal body size, the instilled volume should not exceed 2.0 litres. If this causes stomach pain a smaller volume should be used.

How is Extraneal given:

Extraneal should be introduced into your peritoneal cavity in around 10-20 minutes at a rate that you find most comfortable. It is recommended that Extraneal remains in your body for between 6 and 12 hours in CAPD and 14-16 hours in APD. Drainage of the fluid is by gravity at a rate comfortable for you. The drained fluid should be checked for visible matter and cloudiness. If cloudy, consult your doctor or renal nurse.

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 centre or doctor.

Make sure that the solution is clear and does not contain particles. Do not use bags that are cloudy, leaking or that contain particles.

The bag of Extraneal may be warmed to body temperature prior to use, using a warming device designed for the purpose. The bag should not be immersed in water nor should it be microwaved in order to warm.

Frequency of administration and if applicable most appropriate time to administer Extraneal:

This product is designed to replace one of your daily glucose exchanges. Extraneal is recommended for use overnight in CAPD and during the day APD.

Duration of treatment, if limitable:

This will be determined by your doctor.

What to do if more than 1 dose is missed:

Please contact your doctor for further advice.

How should treatment be stopped, if treatment may lead to withdrawal or other adverse events:

Extraneal should not cause symptoms of withdrawal. If you suffer from an adverse event, your doctor may decide to discontinue Extraneal treatment.

Side Effects

Undesirable effects of peritoneal dialysis include procedure and solution related problems.

Procedure related side effects include: abdominal pain, bleeding, peritonitis, infection around the catheter and catheter blockage.

Solution related side effects include: electrolyte and fluid imbalances, blood volume changes, blood pressure changes, muscle cramping and rashes.

Potential effects of female and male fertility are unknown.

Should you suffer any of the above or any other side effects please inform your doctor or renal nurse.

OVERDOSE

You should not use more than one bag of Extraneal per 24 hours. If you have repetitively used more than one bag per 24 hours, you should consult your doctor as it may affect levels of Icodextrin metabolites in your blood. The doctor will ultimately decide if any corrective treatment is necessary.

STORAGE CONDITIONS

Extraneal has a shelf life of 2 years at temperatures below 30°C.

The product should not be stored below 4°C.

Do not use the product after the expiry date shown on the product label.

Keep out of reach of children.

The product should be used once only.

Any unused portion of dialysate should be discarded.

PRODUCT DESCRIPTION

What Extraneal looks like

Extraneal is a sterile solution for intra-peritoneal administration. It is in a flexible plastic container with or without a second plastic bag attached for drainage. It is available in the following bag size: 2.5 litres.

Ingredients

The active ingredients and excipients of Extraneal formulated in each one litre are listed below.

Active Constituents

- Icodextrin - 75g
- Sodium Chloride - 5.4g
- Sodium Lactate - 4.5g
- Calcium Chloride - 257mg
- Magnesium Chloride - 51mg

Other Ingredients

- Water for injections - q.s.
- Sodium Hydroxide - For pH adjustment
- Hydrochloric Acid - For pH adjustment

Where do you go for further information

You should consult your doctor to discuss any aspect of your treatment.

Manufacturer

Extraneal is manufactured in Australia by **Baxter Healthcare Pty Ltd.**, 1 Baxter Drive, Old Toongabbie, NSW 2146, Australia.

Australian Registration Number

Extraneal (Icodextrin 7.5%) AUST R:

- Single Bag 91344
- Twin Bag 91430

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