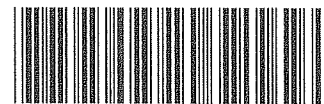


# EXTRANEAL Peritoneal Dialysis Solution

## with 7.5% Icodextrin

For intraperitoneal administration only



**PATIENT LEAFLET**

Dear patient,

Please read this leaflet carefully because it contains important information for you. If you have further questions, please ask your physician or pharmacist.

**Product name**

EXTRANEAL (Icodextrin 7.5%).

**Composition**

**What are the active substances?**

EXTRANEAL is a sterile solution for intraperitoneal administration.

Each 100 ml of EXTRANEAL contains: Electrolyte solution content per 1000 ml:

Icodextrin	7.5 g	Sodium	132 mmol
Sodium Chloride	538 mg	Calcium	1.75 mmol
Sodium Lactate	448 mg	Magnesium	0.25 mmol
Calcium Chloride	25.7 mg	Chloride	96 mmol
Magnesium Chloride	5.08 mg	Lactate	40 mmol

Theoretical osmolarity 284 (milliosmoles per litre).

**Composition in Full**

**What else does EXTRANEAL contain?**

EXTRANEAL also contains:

Water for injections.

**Pharmaceutical form and pharmaco-therapeutic group**

**What is EXTRANEAL?**

EXTRANEAL is a sterile peritoneal dialysis fluid containing Icodextrin as the active ingredient at a concentration of 7.5%, in an electrolyte solution.

EXTRANEAL is a solution for intraperitoneal administration only. It should not be used for intravenous administration.

EXTRANEAL is presented in flexible PVC containers and is available in the following bag sizes:

Code	Fill Volume (mL)	Container Size (mL)	Product Configuration	Pack Size
FNB4974	2000	2000	AMBU-FLEX	6
FNB4982	1500	2000	ULTRABAG	8
FNB4984	2000	2000	ULTRABAG	6

**Marketing Authorisation Holder**

**Who is responsible for marketing EXTRANEAL?**

Baxter Healthcare (Asia) Pte Ltd

10 Hoe Chiang Road, #11-01 Keppel Towers, Singapore 089315

Baxter Healthcare Ltd.

15F, 216 Tun-Hua S. Rd., Sec. 2, Taipei 106, Taiwan

Baxter Incorporated

5th FL., KNT0 Bldg., 10 Da-dong, Chung-gu, Seoul 100-180, Korea

Baxter Healthcare Ltd

Room 2004-6 CRC Protective Tower, 38 Gloucester Road, Wanchai, Hong Kong

**Name and address of the manufacturer**

**Who is responsible for the manufacture of EXTRANEAL?**

Baxter Healthcare SA, Singapore Branch

2 Woodlands Industrial Park D, Singapore 738750

**Properties**

**How does EXTRANEAL work?**

Icodextrin is a starch-derived glucose polymer which acts as an osmotic agent when administered intraperitoneally for continuous ambulatory peritoneal dialysis (CAPD). EXTRANEAL produces sustained ultrafiltration over a period up to 12 hours in CAPD, with a reduction in caloric load compared to 4.25% Dextrose solutions, but with similar volume of ultrafiltrate.

**Therapeutic Indications**

**Why use EXTRANEAL?**

EXTRANEAL is recommended as a once daily replacement for a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for patients who have lost ultrafiltration on Dextrose solutions, because it can extend time on CAPD therapy in such patients.

**Contraindications**

**When should you not use EXTRANEAL?**

EXTRANEAL should not be used if you have a known allergy to starch based polymers or an icodextrin intolerance.

EXTRANEAL should also not be used if you have a history of abdominal surgery in the month preceding commencement of therapy or if you are suffering from abdominal fistulae (non-healing weeping wounds), tumours, open wounds, herniae or other conditions affecting your abdomen.

**Precautions for use**

**What precautions have to be taken?**

EXTRANEAL is for intraperitoneal administration only. To change the dialysis bag, it is of vital importance that you carefully follow the steps which have been shown to you during training, and that you make sure that all the connecting parts remain completely clean to reduce the possibility of infection. To reduce discomfort on administration, the solution should be warmed in the oversealed bag to a temperature of 37°C prior to use. This should be done using dry heat, ideally using a warming plate specially designed for the purpose. Hot water should not be used to warm the bag in order to avoid contamination of connectors.

- An accurate fluid balance record must be kept and your body weight should be carefully monitored to avoid over- and underhydration, which may have severe consequences, including congestive heart failure, volume depletion and shock.

- An aseptic technique should be observed throughout the bag change procedure.

- Significant losses of protein, amino acids and water-soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be prescribed as necessary by your physician.

- Serum electrolyte concentrations (particularly bicarbonate), blood chemistry and haematological factors should be evaluated periodically by your physician.

- If you have diabetes, blood glucose levels should be monitored and the dosage of insulin or other treatment for hyperglycaemia should be adjusted by your physician. It should be noted that EXTRANEAL may interfere with the measurement of blood glucose by certain testing kits. Glucose dehydrogenase pyroloquinolinequinone (GDH-PQQ)-based methods should not be used. A falsely high blood glucose level might be found. If you need to measure your blood glucose levels and you use Extraneal, your physician will advise you on which blood glucose test kit to use, or contact the test kit manufacturer to determine if Extraneal will interfere with blood glucose test results.

In case of doubt on the above precautions, you should not hesitate to consult your physician or pharmacist.

**Special Warnings**

Minor fall in serum sodium and increase in osmolarity.

Increase in plasma level of oligosaccharides and maltose can occur. Long term effects not reported.

**What do you have to consider during pregnancy and while breast feeding?**

EXTRANEAL is not recommended during pregnancy or while breast feeding. Women of childbearing potential should be treated with EXTRANEAL only when adequate contraceptive precautions have been taken. Potential effects on male and female fertility are unknown.

**What needs to be taken into consideration for children?**

EXTRANEAL is not recommended in children.

**What else needs to be taken into consideration?**

There are other conditions which may make the use of EXTRANEAL unsuitable for you, for example conditions affecting your nutrition, breathing or if you have a potassium deficiency. EXTRANEAL should not be used if you have acute renal failure.

The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of infection or aseptic peritonitis. If this occurs, contact your physician or dialysis nurse immediately.

**Interactions with other Medicaments and other forms of Interaction**

**What other products can EXTRANEAL effect?**

The effect of treatment with cardiac glycosides may be affected if taken whilst using EXTRANEAL. Plasma levels of potassium and calcium must therefore be carefully checked by your physician. In the event of abnormal levels, appropriate actions should be taken.

**Other forms of interaction**

See the measurement of blood glucose by certain testing kits under precautions for use.

**Incompatibilities**

**Is EXTRANEAL incompatible with any other medicines?**

There are no known problems with compatibility of EXTRANEAL and other medicines.

A range of antibiotics including vancomycin, cephalosporins, ampicillin/flucloxacillin, ceftazidime, gentamicin, amphotericin, and insulin have shown no evidence of incompatibility with EXTRANEAL.

**Posology and Method of Administration**

**How and when should you use EXTRANEAL?**

Your physician will decide on the dosage of EXTRANEAL.

EXTRANEAL is recommended for use during the longest dwell period, i.e. in CAPD usually overnight and in APD for the long daytime dwell.

Adults: By intraperitoneal administration limited to a single exchange in each 24 hour-period, as part of a CAPD or APD regimen.

Elderly: As for Adults.

Children: Not recommended for use in children (less than 18 years).

The volume to be instilled should be given over a period of approximately 10 to 20 minutes at a rate which the patient finds comfortable. For adult patients of normal body size the instilled volume should not exceed 2.0 litres. If this causes abdominal tension a 1.5 litre volume should be used. The recommended dwell time is 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 the patient. The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of infection or aseptic peritonitis.

**Undesirable Effects**

**What side-effects may EXTRANEAL cause?**

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

- Those which are related to the procedure are abdominal pain, bleeding, cloudy effluents with or without bacteria, aseptic peritonitis (see Special Warnings Section), infection around the catheter, catheter blockage, ileus and shoulder pain. Peritonitis is estimated to occur in between 50% and 70% of all patients during the course of treatment. On average peritonitis occurs once every 1½ - 3 years. The corresponding figure for infection around the catheter is 20% - 30%. The frequency of the other mentioned complications is less.

- Those which are related to peritoneal dialysis solutions are seen less frequently than those related to the procedure and include electrolyte and fluid imbalances, hypo- and hypervolaemia, hypo- and hypertension, muscle cramping and dysequilibrium syndrome.

There have been rare reports of rashes, occasionally associated with exfoliation in patients using other medicines in conjunction with EXTRANEAL.

**What measures are to be taken if side effects occur?**

Should any of the above listed side-effects occur, immediately inform your physician.

If you notice any unwanted effects not mentioned in this leaflet or if you are unsure about the effect of this product, please inform your physician or pharmacist.

**Overdose**

**What to do if you use too much EXTRANEAL?**

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 a physician as it may affect levels of Icodextrin metabolites in your blood. The physician will ultimately decide if any corrective treatment is necessary.

**Special Precautions for Storage**

**How should EXTRANEAL be stored?**

EXTRANEAL has a shelf life of 2 years. Do not use the product after expiry date shown on the carton and product label.

Store at temperature below 30°C. Do not use unless the solution is clear and the container undamaged.

Keep out of reach of children. Any unused portion of dialysis solution in a bag should be discarded.

**Date on which package leaflet was last revised**

PPD-15-790 December 2007

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