

PACKAGE LEAFLET: INFORMATION FOR THE USER

EXTRANEAL Solution for Peritoneal Dialysis

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What EXTRANEAL is and what it is used for
2. What you need to know before you use EXTRANEAL
3. How to use EXTRANEAL
4. Possible side effects
5. How to store EXTRANEAL
6. Contents of the pack and other information

1. WHAT EXTRANEAL IS AND WHAT IT IS USED FOR

EXTRANEAL is a solution for peritoneal dialysis. The peritoneal cavity is the cavity in your abdomen (belly) between your skin and the peritoneum. The peritoneum is the membrane surrounding your internal organs such as your intestines and liver. The EXTRANEAL solution is placed into the peritoneal cavity where it removes water and waste products from the blood. It also corrects abnormal levels of different blood components.

EXTRANEAL may be prescribed for you if:

- You are an adult with permanent kidney failure which needs peritoneal dialysis.
- Standard glucose peritoneal dialysis solutions alone cannot remove sufficient water.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EXTRANEAL

Your doctor must supervise you the first time you use this product.

Do NOT use EXTRANEAL

- if you are allergic to icodextrin or starch derivatives (e.g. maize starch) or any of the other ingredients of EXTRANEAL
- if you are intolerant to maltose or isomaltose (sugar coming from starch)
- if you have glycogen storage disease
- if you already have severe lactic acidosis (too much acid in the blood)
- if you have a surgically uncorrectable problem affecting your abdominal wall or cavity or uncorrectable problem that increases risk of abdominal infections
- if you have documented loss of peritoneal function due to severe peritoneal scarring

Warnings and precautions

Talk to your doctor before using EXTRANEAL

- if you are elderly. There is a risk of dehydration.

- if you are diabetic and using this solution for the first time. You may need to adjust your insulin dose.
- if you need to test your blood glucose level (for example if you are diabetic). Your doctor will advise you on which test kit to use (see “Other forms of interactions”).
- if you have a high risk of severe lactic acidosis (too much acid in the blood). You are at increased risk of lactic acidosis if:
 - you have profoundly low blood pressure
 - you have a blood-infection
 - acute severe kidney failure
 - you have an inherited metabolic disease
 - you are taking metformin (a medicine used to treat diabetes)
 - you are taking medicines to treat HIV, especially medicines called NRTIs
- if you experience abdominal pain or notice cloudiness, haziness or particles in the drained fluid. This may be a sign of peritonitis (inflamed peritoneum) or infection. You should contact your medical team urgently. Note the batch number and bring it along with the drained fluid bag to your medical team. They will decide if the treatment should be stopped or any corrective treatment started. For example if you have an infection your doctor may perform some tests to find out which antibiotic will be best for you. Until your doctor knows which infection you have, he may give you an antibiotic that is effective against a wide number of different bacteria. This is called a broadspectrum antibiotic.
- during peritoneal dialysis your body may lose protein, amino acids, vitamins. Your doctor will know if these need to be replaced.
- if you have problems affecting your abdominal wall or cavity. For example if you have a hernia or a chronic infectious or inflammatory condition affecting your intestines.
- if you had aortic graft placement.
- if you have severe lung disease, e.g. emphysema
- if you have breathing difficulties.
- if you have disorders precluding normal nutrition.
- if you have a potassium deficiency.

You should also take into account that:

- a disorder called encapsulating peritoneal sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. You – possibly together with your doctor – should be aware of this possible complication. EPS causes:
 - inflammation in your abdomen (belly)
 - the growth of sheets of fibrous tissue that cover and bind your organs and affect their normal movement. Rarely this has been fatal.
- you – possibly together with your doctor – should keep a record of your fluid balance and of your body weight. Your doctor will monitor your blood parameters at regular intervals.
- your doctor will check your potassium levels regularly. If they fall too low he may give you some potassium chloride to compensate.

Sometimes treatment with this medicine is not recommended, such as if:

- You have acute kidney disease.

Children

The safety and efficacy of Extraneal in children less than 18 years old has not been demonstrated.

Other medicines and EXTRANEAL

- Tell your doctor if you are taking, have recently taken or might take any other medicines. If you use other medicines, your doctor may need to increase their dose. This is because peritoneal dialysis treatment increases the elimination of certain medicines.
- Take care if you use heart medicines known as cardiac glycosides (e.g. digoxin). Your heart medicine may not be so effective or its toxicity may be increased. You may:
 - need potassium and calcium supplements
 - develop an irregular heartbeat (an arrhythmia)

Your doctor will monitor you closely during treatment, especially your potassium levels.

Other forms of interactions

EXTRANEAL interferes with the measurement of blood glucose with certain testing kits. If you need to test your blood glucose, make sure that you use a kit that is glucose-specific. Your doctor will advise you on which kit to use.

Using the wrong test may cause a falsely high blood glucose reading level. This could result in administration of more insulin than needed. This can cause hypoglycaemia (low blood glucose levels), which can result in loss of consciousness, coma, neurological damage or death. Additionally, a false high glucose reading may mask true hypoglycaemia and allow it to go untreated with similar consequences.

False high glucose readings can be seen up to two weeks after you stopped your Extraneal therapy. In case you are admitted to hospital you should warn the doctors about this possible interaction and they should carefully review the product information of the testing kit to make sure they use a glucose-specific one.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. EXTRANEAL is not recommended during pregnancy or while breast-feeding unless your doctor advises differently.

Driving and using machines

This treatment may cause fatigue, weakness, blurred vision or dizziness. Do not drive or operate machines if you are affected.

3. HOW TO USE EXTRANEAL

EXTRANEAL is to be administered into your peritoneal cavity. This is the cavity in your abdomen (belly) between your skin and the peritoneum. The peritoneum is the membrane surrounding your internal organs such as your intestines and liver.

Always use this medicine exactly as instructed by the medical team specialised in peritoneal dialysis. Check with your doctor if you are not sure.

The recommended dose is

- One bag per day during the longest dwell, i.e.
 - Overnight in Continuous Ambulatory Peritoneal Dialysis (CAPD)
 - During the daytime in Automated Peritoneal Dialysis (APD).
- Take between 10-20 minutes to instill the solution.

- The dwell time with EXTRANEAL is between 6-12 hours in CAPD, and 14-16 hours in APD.

Method of administration

Before use,

- Warm the bag to 37°C. Use the warming plate specially designed for this purpose. Never immerse in water to warm the bag.
- Use aseptic technique throughout the administration of the solution as you have been trained.
- Prior to beginning an exchange, ensure you clean your hands and the area where your exchange will be performed.
- Prior to opening the overpouch, check for the correct solution type, expiration date, and amount (volume). Lift the dialysate bag to check for any leaks (excess fluid in the overpouch). Do not use the bag if leaks are discovered.
- After removing the overpouch, inspect the container for signs of leakage by pressing firmly on the bag. Do not use the bag if any leak is detected.
- Check that the solution is clear. Do not use the bag if the solution is cloudy or contains particles.
- Ensure all connections are secure before beginning the exchange.
- Ask your doctor if you have questions or concerns about this product or how to use it.

Use each bag only once. Discard any unused remaining solution. After use, check that the drained fluid is not cloudy.

Compatibility with other drugs

Your doctor may prescribe you other injectable drugs to be added directly into the EXTRANEAL bag. In that situation, add the drug through the medication site located at the bottom of the bag. Use the product immediately after addition of the drug. Check with your doctor if you are not sure.

If you use more than one bag of EXTRANEAL in 24 hours

If you infuse too much EXTRANEAL you may get:

- abdominal distension
- a feeling of fullness and/or
- a shortness of breath.

Contact your doctor immediately. He will advise you what to do.

If you stop using EXTRANEAL

Do not stop peritoneal dialysis without the agreement of your doctor. If you stop the treatment it may have life-threatening consequences.

4. POSSIBLE SIDE EFFECTS

Like all medicines, EXTRANEAL can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

If any of the following happen, tell your doctor or your peritoneal dialysis centre immediately:

- Hypertension (blood pressure that is higher than usual),

- Swollen ankles or legs, puffy eyes, shortness of breath or chest pain (hypervolaemia),
- Hypersensitivity (allergic reaction) which may include swelling of face, throat or around the eyes (angioedema)
- Abdominal pain,
- Chills (shivering/flu-like symptoms).

These could be signs of serious side effects. You may need urgent medical attention.

Side effects commonly observed (may affect up to 1 in 10 people) in patients using EXTRANEAL:

- Redness and scaling of the skin, rash, itching (pruritus)
- Feeling light headed or dizzy, thirst (dehydration)
- Decreased blood volume (hypovolaemia)
- Abnormal laboratory tests
- Weakness, headache, fatigue
- Swollen ankles or legs,
- Low blood pressure (hypotension)
- Ringing in the ears

Other side effects related to the peritoneal dialysis procedure or common to all peritoneal dialysis solutions:

- Cloudy solution drained from the peritoneum, stomach-ache
- Peritoneal bleeding, pus, swelling, pain or infection around the exit site of your catheter, catheter blockage, injury, interaction with the catheter.
- Low blood sugar concentration (hypoglycaemia)
- Shock or coma caused by low blood sugar concentration
- High blood sugar concentration (hyperglycaemia)
- Nausea, vomiting, loss of appetite, dry mouth, constipation, diarrhoea, flatulence (passing wind), disorder of the stomach or intestines such as blockage in your intestine, gastric ulcer, gastritis (inflamed stomach), indigestion.
- Abdominal swelling, hernia of the abdominal cavity (this causes a lump in the groin)
- Modification of your blood tests
- Abnormal liver function test
- Weight increase or decrease
- Pain, fever, malaise
- Heart disease, faster heart beat, shortness of breath or chest pain
- Anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness); increase or decrease of white blood cell count; reduction in blood platelets, which increases risk of bleeding or bruising
- Numbness, tingling, burning sensation
- Hyperkinesia (increased movements and inability to keep still)
- Blurred vision
- Loss of the sense of taste
- Fluid on the lungs (pulmonary oedema), shortness of breath, difficulty in breathing or wheezing, cough, hiccups
- Kidney pain
- Nail disorder
- Skin disorders such as hives (urticaria), psoriasis, skin ulcer, eczema, dry skin, skin discoloration, blistering of the skin, allergic or contact dermatitis, rashes and itching.
- Rashes may be itchy with red spots covered with bumps, or with eruptions or shedding of the skin. The following three severe types of skin reaction may occur:
 - Toxic epidermal necrolysis (TEN). This causes:
 - a red rash over many parts of the body
 - the shedding of the outer layer of skin

- Erythema multiforme. An allergic skin reaction causing spots, red welts or purple or blistered areas. It can also affect the mouth, eyes and other moist body surfaces.
- Vasculitis. Inflammation of certain blood vessels within the body. Clinical symptoms will depend on the part of the body involved, but may be characterized on the skin as red or violet spots or welts or have symptoms similar to an allergic reaction, including rash, joint pain and fever
- Muscle cramps, pain in bones, joints, muscles, back, neck
- Fall in blood pressure on standing up (orthostatic hypotension)
- Peritonitis (inflamed peritoneum) including peritonitis caused by fungal or bacterial infection
- Infections including flu syndrome, boil
- Abnormal thinking, anxiety, nervousness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

Republic of Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

United Kingdom (Northern Ireland)

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EXTRANEAL

- Keep out of the sight and reach of children.
- Store in the original package.
- Do not store below 4°C.
- Do not use EXTRANEAL after the expiry date. The date is stated on the carton label and on the bag after the abbreviation Exp. and the symbol ☞. The expiry date refers to the last day of that month.
- Dispose Extraneal as you have been trained.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor.

What EXTRANEAL contains

The active substances are:

Icodextrin	75 g/l
Sodium chloride	5.4 g/l

Sodium S-lactate	4.5 g/l
Calcium chloride	0.257 g/l
Magnesium chloride	0.051 g/l

Sodium	133 mmol/l
Calcium	1.75 mmol/l
Magnesium	0.25 mmol/l
Chloride	96 mmol/l
Lactate	40 mmol/l

The other ingredients are:

- Water for injections.
- Sodium hydroxide or hydrochloric acid.

What EXTRANEAL looks like and contents of the pack

- EXTRANEAL is packaged in flexible plastic bags of 1.5 litres, 2.0 litres or 2.5 litres capacity.
- The solution in the bags is clear and colourless.
- Each bag is over-wrapped in an overpouch and supplied in carton boxes.

Volume	Number of units per box	Product configuration	Type of connector(s)
1.5L	8	Single bag (APD)	luer / spike
1.5L	8	Twin bag (CAPD)	luer / spike
1.5L	6	Single bag (APD)	luer / spike
1.5L	6	Twin bag (CAPD)	luer / spike
2.0L	8	Single bag (APD)	luer / spike
2.0L	8	Twin bag (CAPD)	luer / spike
2.0L	6	Single bag (APD)	luer / spike
2.0L	6	Twin bag (CAPD)	luer / spike
2.0L	5	Single bag (APD)	luer / spike
2.0L	5	Twin bag (CAPD)	luer / spike
2.5L	5	Single bag (APD)	luer / spike
2.5L	5	Twin bag (CAPD)	luer / spike
2.5L	4	Single bag (APD)	luer / spike
2.5L	4	Twin bag (CAPD)	luer / spike

Not all configurations may be marketed.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Marketing Authorisation Holder

United Kingdom (Northern Ireland):

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**For information about EXTRANEAL or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder:
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