

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

## Extraneal®

### Solution for peritoneal dialysis

Composition:

Each liter of solution contains:

icodextrin	75 g
sodium chloride	5.4 g
sodium (s) - lactate	4.5 g
calcium chloride dihydrate	0.257 g
magnesium chloride hexahydrate	0.051 g

Electrolytes in one liter:

sodium	133 mmol
calcium	1.75 mmol
magnesium	0.25 mmol
chloride	96 mmol
lactate	40 mmol

For information about inactive ingredients see section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

**This medicine is not intended for use in children and adolescents (under 18 years of old).**

#### 1. What is this medicine intended for?

Extraneal is a solution for peritoneal dialysis, to be used once a day in patients with chronic kidney failure. Extraneal solution is placed in the peritoneal cavity. Extraneal solution makes it possible to remove excess water and waste products from the blood, and correct abnormal levels of substances that are dissolved in the blood.

#### Therapeutic group:

isotonic solutions for peritoneal dialysis.

#### 2. Before using this medicine

You will need medical supervision the first time you use this product.

##### Do not use this medicine if:

- you are sensitive (allergic) to icodextrin or starch derivatives or any of the other ingredients in Extraneal (see section 6).
- you are intolerant to maltose or isomaltose (sugar coming from starch).
- you have glycogen storage disease.
- you have severe lactic acidosis (too much acid in the blood).
- you have a surgically uncorrectable problem affecting your abdominal wall or cavity or an uncorrectable problem that increases risk of abdominal infections.
- you have documented loss of peritoneal function due to severe peritoneal scarring.

#### Special warnings about using this medicine

**Before you start treatment with Extraneal tell your doctor if:**

- You are elderly. There is a risk of dehydration.
- You are diabetic and using this solution for the first time. You may need to adjust your insulin dose.
- You need to test your blood glucose level (for example if you are diabetic). Your doctor will advise you which test kit to use (see 'Tests and follow-up').
- You are at a high risk of developing severe lactic acidosis (too much acid in the blood). You are at increased risk of lactic acidosis if:
  - you have very low blood pressure
  - you have a blood infection
  - you have 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 (nucleoside/nucleotide reverse transcriptase inhibitors)
- You experience abdominal pain or notice cloudiness or particles in the drained fluid. This may be a sign of peritonitis (inflamed peritoneum) or infection. Contact your medical team urgently. Note the batch number and bring the drained fluid bag to your medical team. They will decide if the treatment should be stopped or if you need supportive treatment.
- During peritoneal dialysis your body may lose protein, amino acids, vitamins. Your doctor will decide if you need to take supplements.
- 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.
- You had an aortic valve implantation.
- You have a severe lung disease such as emphysema.
- You have breathing difficulties.
- You have disorders precluding normal nutrition.
- You have a potassium deficiency.

#### You should also take into account that:

- Encapsulating peritoneal sclerosis (EPS) is a rare complication of peritoneal dialysis. You and your doctor should be aware of the possible complications. EPS causes:
  - inflammation in your abdomen.
  - thickening of the layers of connective tissue that cover and bind your organs and affect their normal movement. In rare cases, this condition is life-threatening.
- You and your doctor should keep a record of your fluid balance and of your body weight. Your doctor will monitor parameters in your blood regularly.
- Your doctor will monitor your potassium levels regularly. If they fall too low your doctor may decide to give you suitable treatment.

Sometimes treatment with this medicine is not recommended, for example if:

- you have acute kidney disease.

#### Children and adolescents

If you are younger than 18 years old, treatment with this medicine is not recommended.

#### Other medicines and Extraneal

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**

- If you are taking other medicines, your doctor may need to increase their dose. This is because peritoneal dialysis treatment increases the elimination of certain medicines from your body.
- Caution is necessary if you take medicines known as cardiac glycosides (such as digoxin) for heart problems. Your heart medicine may not be effective enough or its toxicity may increase. You may:
  - need potassium and calcium supplements.
  - experience an irregular heartbeat (arrhythmia).Your doctor will monitor you closely during treatment, especially your potassium levels.

#### Tests and follow-up

Extraneal interferes with the measurement of blood glucose with certain test 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 which kit to use.

Using the wrong kit to measure glucose may cause a falsely high blood glucose reading. This could result in administration of more insulin than needed which can cause hypoglycemia (low blood glucose levels). Hypoglycemia can result in loss of consciousness, coma, neurological damage or death. Additionally, a false high glucose reading may mask true hypoglycemia 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. If you are admitted to hospital, tell the doctors about this possible interaction so they can make sure they use a glucose-specific test kit.

#### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 breastfeeding 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 feel these effects.

#### 3. How to use this medicine?

Always use this medicine according to your doctor's instructions and those of the medical team specialized in peritoneal dialysis. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

**Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:**

- One bag per day during the longest dwell (the period of time the solution remains in the peritoneal cavity).
- The dwell time with Extraneal is between 6-12 hours in CAPD (manual treatment), and 14-16 hours in APD (machine treatment).

#### How to use the medicine

Before use:

- Warm the bag to 37°C. Only use dry heat (follow the

directions you are given). Never immerse the bag in water to warm it.

- Make sure to clean your hands and the area where your exchange will be performed.
- Before opening the outer pouch, check the solution type, expiration date, and amount (volume). Lift the dialysis bag to check for any leaks (excess fluid in the outer pouch). Do not use the bag if leaks are discovered.
- After removing the outer pouch, inspect the container for signs of leakage by pressing firmly on the bag. Do not use the bag if leaks are discovered.
- Check that the solution is clear. Do not use the bag if the solution is cloudy or contains particles.
- Make sure that all connections are secure before beginning the exchange.

Use each bag only once. Discard any unused remaining solution.

After use:

check that the drained fluid is not cloudy.

#### Compatibility with other medicines:

Your doctor may prescribe you other injectable drugs to be injected directly into the Extraneal bag. In this case, add the medicine through the designated place at the bottom of the bag. Use the bag immediately after adding the medicine.

Check with your doctor if you are not sure.

#### If you accidentally use more than one bag of Extraneal in 24 hours

If you infuse too much Extraneal you may get

- bloating
- a feeling of fullness
- shortness of breath

Immediately consult your doctor who will tell you what you should do.

Adhere to the treatment as recommended by your doctor.

#### If you stop your Extraneal treatment

Do not stop peritoneal dialysis without consulting your doctor. Stopping the treatment may have life-threatening consequences.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### 4. Side effects

Like with all medicines, using Extraneal may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**If you experience any of the following side effects, tell your doctor or your peritoneal dialysis center immediately:**

- hypertension (blood pressure that is higher than usual)
- swollen ankles or legs, puffy eyes, shortness of breath or chest pain (hypervolemia)
- 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.

#### Additional side effects:

**Common side effects (may affect up to 1 in 10 patients):**

- redness and scaling of the skin, rash, itching
- feeling light headed or dizzy, thirst (dehydration)
- decreased blood volume (hypovolemia)
- abnormal laboratory tests
- weakness, headache, fatigue
- swollen ankles or legs
- low blood pressure
- 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, reaction to contact with the catheter
- low blood sugar concentration (hypoglycemia)
- shock or coma caused by low blood sugar concentration
- high blood sugar concentration (hyperglycemia)
- nausea, vomiting, loss of appetite, dry mouth, constipation, diarrhea, 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)
- changes in your blood tests
- abnormal results of liver function test
- gaining or losing weight
- pain, fever, weakness
- heart disease, faster heart beat, shortness of breath or chest pain
- anemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness); increase or decrease in 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 buildup in the lungs (pulmonary edema), shortness of breath, difficulty in breathing or wheezing, cough, hiccups
- kidney pain
- problems with your nails
- 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 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
    - peeling 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 some of the blood vessels in the body. Clinical symptoms will depend on the body part that is inflamed. Skin symptoms may appear as red or purple spots or bruises, sores, or have symptoms similar to an allergic reaction, including rash, joint pain and fever.
- Muscle cramps, pain in bones, joints, muscles, back, or neck
- Drop in blood pressure on standing up (orthostatic hypotension)
- Peritonitis (inflamed peritoneum) caused by fungal or bacterial infection
- Infections including flu, pus-filled sore
- Abnormal thoughts, anxiety, irritability

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

#### Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page [www.health.gov.il](http://www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

#### 5. How to store the medicine?

- **Prevent poisoning!** To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

#### Storage conditions

- **Store at 4°C-25°C.**
- Do not use unless the solution is clear and the package is undamaged.
- Store in the original package.
- Use this medicine immediately after the outer cover has been removed.
- Ask your pharmacist how to dispose of medicines you no longer use.

#### 6. Additional information

**In addition to the active ingredients, this medicine also contains:**

sodium chloride or hydrochloric acid (for pH adjustment), water for injection.

#### What the medicine looks like and contents of the pack

- A clear and colorless solution in a plastic bag packaged in an outer bag (pouch)
- Each package contains 2 or 2.5 liters. Not all pack sizes may be marketed.

**Registration holder's name and address:** Teva Medical (Marketing) Ltd., 8 Haorglim Street, Ashdod

**Manufacturer's name and address:** Baxter Healthcare SA, Castlebar, Ireland

This leaflet was reviewed and approved by the Ministry of Health in May 2013 and revised in July 2019 in accordance with Ministry of Health guidelines.

**Registration number of the medicine in the Ministry of Health's National Drug Registry:** 116.27.29763