

Package leaflet: Information for the user

Nutrineal PD4 1.1% Amino Acids Clear-Flex Solution for peritoneal dialysis

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

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

1. What Nutrineal is and what it is used for

Nutrineal is a solution for peritoneal dialysis which does not contain glucose. It removes water and waste products from the blood and corrects different abnormal components of blood.

Nutrineal may be prescribed for you:

- if you have kidney failure which needs peritoneal dialysis
- in particular if you are malnourished.

2. What you need to know before you use Nutrineal

Your doctor will assess whether Nutrineal is a suitable solution for your peritoneal dialysis treatment. He will have taken into account any factors in your medical history which might exclude the use of peritoneal dialysis solutions.

Do not use Nutrineal

You must NOT use Nutrineal

- If you are allergic to any amino acids or any of the other ingredients of this medicine (listed in section 6).
- If your blood urea level is above 38 mmol/l.
- If you suffer from a disorder affecting amino acid metabolism.
- If your blood potassium level is too low.
- If you show uraemic symptoms such as loss of appetite, nausea or vomiting.
- If your blood bicarbonate levels are too low.
- If you suffer from severe liver insufficiency.
- 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.

Warnings and precautions

Talk to your doctor:

- If you experience loss of appetite, nausea or vomiting. Your doctor may need to reduce the number of Nutrineal exchanges or stop Nutrineal treatment.
- 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.
- If you experience a hypersensitivity reaction (an allergic reaction) – see also section 4. Your doctor may need to stop Nutrineal treatment.
- Since, 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 use insulin or any other treatments for correcting hyperglycaemia. Your doctor may need to adjust their dose.
- If you are undergoing treatment for secondary hyperparathyroidism, your doctor will decide if you can use a dialysis solution with a low calcium content.
- 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.
- Your doctor will check your potassium levels regularly. If they fall too low he may give you some potassium chloride to compensate.
- Your doctor will advise you about particular precautions as it applies to you. He will monitor your blood parameters at regular intervals. He will ensure that they are adequate during your treatment.
- You – possibly together with your doctor - should keep a record of your dietary protein intake, your fluid balance and your body weight.

Other medicines and Nutrineal

- 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, calcium and magnesium levels.

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 using this medicine.

Pregnancy

There are no experiences from the use of Nutrineal in pregnant women. If you are pregnant, you will receive this medicine only if your doctor considers it absolutely necessary for your recovery. Nutrineal should only be given to pregnant women after careful consideration.

Breast-feeding

It is not known if Nutrineal passes into your breast milk. Nutrineal is not recommended while breast-feeding unless your doctor advises differently.

Driving and using machines

This treatment may cause weakness, malaise or reduction in body fluid volume (hypovolaemia). Do not drive or operate machines if you are affected.

3. How to use Nutrineal

Nutrineal 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.

Nutrineal is not for intravenous use.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

In case of damage, you should discard the bag.

How much and how often

Your doctor will prescribe you the appropriate number of bags you must use. Usually, it is one bag of 2.5 litres every day.

Use in children and adolescents

If you are below 18 years, your doctor will assess carefully the prescription of Nutrineal.

Your doctor will re-evaluate your treatment after 3 months if there is no improvement in your nutritional status.

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. Never use a microwave oven 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 Nutrineal bag. In that situation, add the drug through the medication site. 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 Nutrineal in 24 hours

If you infuse too much Nutrineal you may get:

- abdominal distension
- a feeling of fullness

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

If you stop taking Nutrineal

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

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effects, talk to your doctor. This includes any side effects not listed in this leaflet.

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

- Abdominal pain.

Very common side effects (occurs in more than 1 in 10 patients treated with Nutrineal):

- Nausea, vomiting
- Anorexia (prolonged disorder of eating due to loss of appetite)
- Gastritis (inflamed stomach)
- Feeling of weakness
- increase in body fluid volume (hypervolaemia)
- High level of acidic substances in the body (acidosis).

Common side effects (occurs in more than 1 in 100 patients treated with Nutrineal):

- Anaemia
- Depression
- Shortness of breath
- Abdominal pain
- Reduction in body fluid volume (hypovolaemia)
- Decrease in potassium salt blood level (hypokalaemia).
- Infection.

Side effects that have been reported (occurs in an unknown number of patients treated with Nutrineal):

- Peritonitis
- Peritoneal Cloudy effluent
- Abdominal discomfort
- Fever
- Malaise
- Itching
- Hypersensitivity reaction (an allergic reaction)
- Serious allergic reaction which causes swelling of the face or throat (angioedema).

Other side effects related to the peritoneal procedure:

- Infection around the exit site of your catheter,
- Catheter related complication
- Decrease in calcium blood level (hypocalcaemia).

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting


Website: www.medicinesauthority.gov.mt/adrportal**Republic of Ireland**

HPRA Pharmacovigilance, Earlsfort Terrace, IRE – Dublin 2.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie;E-mail: medsafety@hpra.ie**UK**

Yellow Card Scheme

www.mhra.gov.uk/yellowcard**5. How to store Nutrineal**

- Keep this medicine out of the sight and reach of children.
- Store in the original package.
- Do not store below 4°C.
- Do not use this medicine after the expiry date which is stated on the carton and on the bag after EXP. and the symbol . The expiry date refers to the last day of that month.

Dispose Nutrineal 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 Nutrineal PD4 1.1% AMINO ACIDS contains

The formula is

Formula in mg/l	
Blend of Amino Acids:	
Alanine	951
Arginine	1071
Glycine	510
Histidine	714
Isoleucine	850
Leucine	1020
Lysine, HCl	955
Methionine	850
Phenylalanine	570
Proline	595
Serine	510
Threonine	646
Tryptophan	270
Tyrosine	300
Valine	1393
Sodium chloride	5380
Calcium chloride dihydrate	184

Magnesium chloride hexahydrate	51
Sodium (S)-lactate solution equivalent to Sodium (S)-lactate	4480
Composition in mmol/l	
Amino Acids	87.16
Na ⁺	132
Ca ⁺⁺	1.25
Mg ⁺⁺	0.25
Cl ⁻	105
C ₃ H ₅ O ₃ ⁻	40

The other ingredients are:

- Water for Injections
- Hydrochloric acid, dilute.

What Nutrineal looks like and contents of the pack

- Nutrineal is packed in a non-PVC plastic bag of 2.5 litres capacity.
- Each bag is over-wrapped in an overpouch and supplied in carton boxes.

Volume	Number of units per box	Product configuration
2.5 L	3	Single bag
2.5 L	4	Single bag

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 and Manufacturer

Baxter Healthcare Ltd,
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

Manufacturers

Baxter Healthcare S.A.
Moneen Road
Castlebar
County Mayo - Ireland

Bieffe Medital SpA,
Via Nuova Provinciale
23034 Grosotto,
Italy

This medicinal product is authorised in the member States of the EEA under the following names:

Austria	NUTRINEAL® PD4 1.1% Amino Acids CLEAR-FLEX®
Belgium	NUTRINEAL® PD4 1.1% Amino Acids CLEAR-FLEX®
Bulgaria	NUTRINEAL PD4 CLEAR-FLEX разтвор за перитонеална диализа
Croatia	NUTRINEAL PD4 CLEAR-FLEX otopina za peritonejsku dijalizu
Cyprus	NUTRINEAL PD4 CLEAR-FLEX, Διάλυμα περιτοναϊκής διαπίδυσης (κάθαρσης)
Czech Republic	NUTRINEAL PD4 CLEAR-FLEX, roztok pro peritoneální dialýzu
Denmark	Nutrineal PD4 1,1 Amino Acids Clear-Flex, peritonealdialysevæske
Estonia	NUTRINEAL PD4 CLEAR-FLEX
Finland	Nutrineal PD4 1,1 % Amino Acids Clear-Flex peritoneaaldialyysineste.
France	NUTRINEAL PD4 A 1,1 % D'ACIDES AMINES CLEAR-FLEX, solution pour dialyse péritonéale

Germany	NUTRINEAL® PD4 mit 1.1% Aminosäuren Peritonealdialyselösung im CLEAR-FLEX®-Beutel
Greece	NUTRINEAL® PD4 1.1% Amino Acids CLEAR-FLEX®
Hungary	NUTRINEAL PD4 CLEAR-FLEX peritoneális dializáló oldat
Iceland	Nutrineal PD4 1,1% Amino Acids Clear-Flex Kviðskilunarlausn
Ireland	NUTRINEAL PD4 1.1% Amino Acids Clear-Flex, Solution for Peritoneal Dialysis
Italy	“NUTRINEAL” 1,1% aminoacidi
Latvia	NUTRINEAL PD4 CLEAR-FLEX šķīdums peritoneālai dialīzei
Lithuania	NUTRINEAL PD4 CLEAR-FLEX peritoninės dializės tirpalas
Luxembourg	NUTRINEAL® PD4 1.1% Amino Acids CLEAR-FLEX®
Malta	NUTRINEAL PD4 CLEAR-FLEX solution for peritoneal dialysis
Netherlands	NUTRINEAL® PD4 1.1% Amino Acids CLEAR-FLEX®
Norway	NUTRINEAL® PD4 1.1% Amino Acids CLEAR-FLEX®
Poland	NUTRINEAL PD4 CLEAR-FLEX
Portugal	Nutrineal PD4 1,1% Aminoácidos Clear-Flex
Romania	NUTRINEAL PD4 CLEAR-FLEX, soluție pentru dializă peritoneală
Slovakia	NUTRINEAL PD4 CLEAR-FLEX, roztok na peritoneálnu dialyze
Slovenia	NUTRINEAL PD4 CLEAR-FLEX, raztopina za peritonealno dializo
Spain	NUTRINEAL® PD4 1.1% Amino Acids CLEAR-FLEX®
Sweden	Nutrineal PD4 1,1 % Aminosyror Clear-Flex, peritonealdialysvätska
United Kingdom	NUTRINEAL PD4 1.1% Amino Acids Clear-Flex, Solution for Peritoneal Dialysis

This leaflet was last revised in 03/2016.

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