Baxter

HOMECHOICE CLARIA APD SYSTEM

DESIGNED TO ENHANCE **APD THERAPY** FROM THE INSIDE OUT

Homechoice Claria

Making possible personal.

HOMECHOICE CLARIA APD SYSTEM FROM BAXTER

BRINGING THE CLINIC TO YOUR PATIENTS

250 MILLION EXCHANGES AND COUNTING

Since 1994 the Homechoice automated peritoneal dialysis (APD) cycler has been the most widely prescribed APD cycler. It has become an established market leader in 97 countries.[1] Today, over 75,000 patients worldwide use it on a daily basis.[1]

THE HOMECHOICE CYCLER IS NOW EVEN BETTER

Homechoice Claria is our next generation cycler that simplifies APD for both patients and HCPs. We've taken all the proven features and made them even more accommodating.[1]

extraneal

THE OPTIMAL SOLUTION FOR THE LONG DWELL

Glucose-free solution[2]

- Provides superior water and sodium removal compared to a 2.27% glucose solution[3]
- Improves fluid balance[3]
- Reduces carbohydrate absorption[4]
- Preserves the peritoneal membrane transport status[5,6]
- Improves small and middle molecule clearance[5,7]
- Clinically proven treatment benefits and safety in combination with PD solutions from Baxter[9,10]

Extraneal offers patients significant benefits over conventional glucose-based solutions.

nutrineal

THE ONLY NON-GLUCOSE SOLUTION FOR THE SHORT DWELL

Glucose-free, effective PD solution[11,12]

- Reduces glucose exposure from the first day of treatment[13]
- More biocompatible solution[14]
- Clinically proven treatment benefits and safety in combination with PD solutions from Baxter[12,13]

Nutrineal is an effective non-glucose solution with amino acids as the osmotic agent allowing the reduction of glucose exposure in your PD patients.

physioneal

SOLUTION FOR A NATURAL MEMBRANE

Improve patient comfort – patients reportedly feel better[17,18]

Maintain acid-base balance[18,19]
Important biocompatible attributes:[17,20,21,22]

- physiological pH
- physiological bicarbonate levels
- physiological pCO2
- low levels of GDPs

Clinically proven treatment benefits and safety in combination with Extraneal and Nutrineal[13]

Physioneal is a PD solution that improves patients' well-being and maintains acid-base balance.

HOMECHOICE CLARIA APD SYSTEM FROM BAXTER

PD YOU CAN TRUST
DELIVERING BENEFITS YOU CAN BELIEVE

THE HOMECHOICE CLARIA APD SYSTEM IS:

Patients treated with PD have better early survival than those treated with conventional haemodialysis[23-26]

- PD may help avoid vascular access and associated morbidity[27]
- Designed for a smoother lifestyle transition compared to conventional hemodialysis[28-30]
- Flexibility to travel

A balance of comprehensive, thoroughly researched data were used to support all points regarding PD.

FEATURES YOU KNOW AND TRUST

The Homechoice Claria APD system continues to leverage the proven performance that has made Homechoice one of the most trusted names in PD therapy.

Pediatric capability

Safety and flexibility

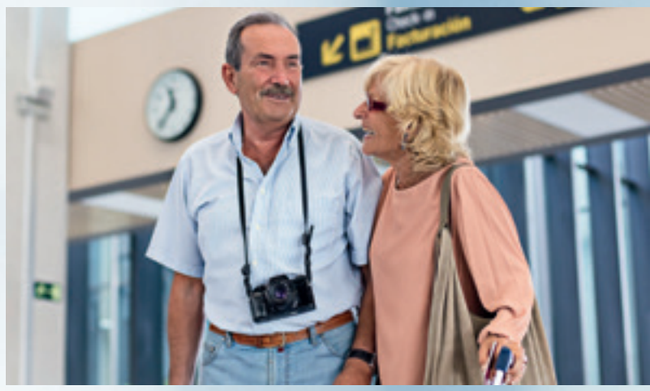
- Advanced Drain Logic “standard” and “low-fill” specific modes[8]
- Allowable ranges and default settings for Tidal Therapies[8]
- Smart Dwells helps to maximise dialysis time[8]
- Built-in logarithms designed to reduce increased intraperitoneal volume (IIPV) and alert the prescriber[8]
- Dedicated nurse menu[8]
- Wide range of programming options and variable configurations allow therapy programs to be tailored to the needs of most patients[8]

Quality of life

- Lightweight, portable and designed for tabletop operation, making it convenient for travel[8]
- Self-correcting alarm management software[8]

User-friendly display

- A 2-line OLED screen that eliminates alternating messages and improves the user experience[1,8]
- Screen design upgraded to improve visibility from multiple angles[1,8]
- Screen size now 100% larger than international display[1,8]
- Inclusive of a wider patient population with multiple new languages added (38 total)
- Informational displays for patients before, during and after treatments
- Auto-dim screen[8]



HERE FOR YOU
HERE FOR YOUR PATIENTS

THREE REASONS TO RELY ON BAXTER PD.

ONE COMPREHENSIVE PORTFOLIO

Since 1978, Baxter has been – and still is – the leader in pioneering breakthrough APD and continuous ambulatory peritoneal dialysis (CAPD) therapy technologies. We recognize that each patient's long-term success on renal replacement therapy depends on finding the optimal combination of therapy choices to suit their clinical and lifestyle needs.

The unique Baxter portfolio brings together trusted cyclers, non-glucose solutions and low glucose therapy combinations coupled with our service and support. This "Combination for Success" makes therapy more accessible and more satisfactory for patients while supporting clinic efficiencies and workflow.

COMBINATION FOR SUCCESS

Homechoice Claria

- 38 languages
- Pediatric capability
- Improved display visibility

extraneal, nutrineal, physioneal*

- Low-glucose therapy combinations and unique non-glucose PD solutions
- Only non-glucose solution for the long dwell
- Only non-glucose solution for the short dwell
- Only PD solution proven to improve patient comfort[17]
- Most widely used osmotic agent in PD

Baxter

- With our comprehensive service and support, you and your patients have access to a network of knowledgeable Baxter experts at every therapy touchpoint

* Not all solutions are available in all markets.

THE SUPPORT PATIENTS NEED TO SUCCEED

Delivery & Inventory Services
Experienced logistics teams provide inventory management, product rotation and personalized delivery schedules for patients.

On-Call Support
Friendly technical support staff are available 24/7 to quickly address patients' needs and minimize concerns.

SWAP Program
If a device is in need of service that requires it to be sent back to Baxter, a substitute device will be provided while the original is being fixed.

Training Programs
Experienced clinical coordinators give healthcare providers hands-on device training – and the confidence to send more patients home on PD.

Baxter Travel Club

- Facilitates travel to over 180 countries
- Provides the transportation and delivery of solutions and/or cyclers to a patient's destination in approved countries

A TEAM DESIGNED AROUND YOU

Medical Support & Education
Subject matter experts, including scientists, interact with health practitioners on a peer-to-peer basis, driving collaborative research and development as it applies to PD. In addition, we offer a range of Baxter clinical training programs around the world.

Clinical PD Consulting
Qualified clinical nurses identify areas of improvement, share best practices and provide best-in-class clinician education.

Prescribing Information

physioneal

ABBREVIATED PRESCRIBING INFORMATION

Physioneal 35 Solution for peritoneal dialysis

PHYSIONEAL 35 Clear-Flex, Solution for peritoneal dialysis

Physioneal 40 Solution for peritoneal dialysis

Physioneal 40 Clear-Flex, Solution for peritoneal dialysis

This abbreviated summary of product characteristics (SPC) is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet.

NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 35 Glucose 1.36% w/v / 13.6 mg/ml
PHYSIONEAL 35 Glucose 2.27% w/v / 22.7 mg/ml
PHYSIONEAL 35 Glucose 3.86% w/v / 38.6 mg/ml
Physioneal 35 Glucose 1.36% w/v / 13.6 mg/ml Clear-Flex
Physioneal 35 Glucose 2.27% w/v / 22.7 mg/ml Clear-Flex
Physioneal 35 Glucose 3.86% w/v / 38.6 mg/ml Clear-Flex
PHYSIONEAL 40 Glucose 1.36% w/v / 13.6 mg/ml
PHYSIONEAL 40 Glucose 2.27% w/v / 22.7 mg/ml
PHYSIONEAL 40 Glucose 3.86% w/v / 38.6 mg/ml
PHYSIONEAL 40 Glucose 1.36% w/v / 13.6 mg/ml Clear-Flex
PHYSIONEAL 40 Glucose 2.27% w/v / 22.7 mg/ml Clear-Flex
PHYSIONEAL 40 Glucose 3.86% w/v / 38.6 mg/ml Clear-Flex

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances: Glucose monohydrate, Sodium Chloride, Calcium chloride dehydrate, Magnesium chloride hexahydrate, Sodium bicarbonate, Sodium (S)-lactate solution

Physioneal 35 and 40 Clear-Flex: 1000 ml of final solution after mixing corresponds to 750 ml of solution A and 250 ml of solution B. The pH of the final solutions is 7.4.

Physioneal 35 and 40: 1000 ml of final solution after mixing corresponds to 362.5 ml of solution A and 637.5 ml of solution B. The pH of the final solutions is 7.4.

After mixing

PHYSIONEAL 35:

Composition of the final solution after mixing in mmol/l	Glucose 1.36% w/v / 13.6 mg/ml	Glucose 2.27% w/v / 22.7 mg/ml	Glucose 3.86% w/v / 38.6 mg/ml
Glucose anhydrous ($C_6H_{12}O_6$)	75.5 mmol/l	126 mmol/l	214 mmol/l
Na^+	132 mmol/l	132 mmol/l	132 mmol/l
Ca^{++}	1.75 mmol/l	1.75 mmol/l	1.75 mmol/l
Mg^{++}	0.25 mmol/l	0.25 mmol/l	0.25 mmol/l
Cl^-	101 mmol/l	101 mmol/l	101 mmol/l
HCO_3^-	25 mmol/l	25 mmol/l	25 mmol/l
$C_3H_5O_3^-$	10 mmol/l	10 mmol/l	10 mmol/l
Osmolarity	345 mOsmol/l	396 mOsmol/l	484 mOsmol/l

PHYSIONEAL 40:

Composition of the final solution after mixing in mmol/l	Glucose 1.36% w/v / 13.6 mg/ml	Glucose 2.27% w/v / 22.7 mg/ml	Glucose 3.86% w/v / 38.6 mg/ml
Glucose anhydrous ($C_6H_{12}O_6$)	75.5 mmol/l	126 mmol/l	214 mmol/l
Na^+	132 mmol/l	132 mmol/l	132 mmol/l
Ca^{++}	1.25 mmol/l	1.25 mmol/l	1.25 mmol/l
Mg^{++}	0.25 mmol/l	0.25 mmol/l	0.25 mmol/l
Cl^-	95 mmol/l	95 mmol/l	95 mmol/l
HCO_3^-	25 mmol/l	25 mmol/l	25 mmol/l
$C_3H_5O_3^-$	15 mmol/l	15 mmol/l	15 mmol/l
Osmolarity	344 mOsmol/l	395 mOsmol/l	483 mOsmol/l

The number '35' in the name specifies the buffer concentration of the solution (10 mmol/l of lactate + 25 mmol/l of bicarbonate = 35 mmol/l).

The number '40' in the name specifies the buffer concentration of the solution (15 mmol/l of lactate + 25 mmol/l of bicarbonate = 40 mmol/l).

Clear-Flex: List of Excipients: Hydrochloric acid dilute(pH adjuster), Sodium hydroxide (pH adjuster), Water for Injections.

PVC: List of excipients: Carbon dioxide (for pH adjustment), Water for injections.

CLINICAL PARTICULARS

Therapeutic indications

PHYSIONEAL 35 is indicated whenever peritoneal dialysis is employed, including:

- Acute and chronic renal failure
- Severe water retention
- Severe electrolyte imbalance
- Drug intoxication with dialysable substances, when a more adequate therapeutic alternative is not available.

PHYSIONEAL 35 bicarbonate/lactate based peritoneal dialysis solutions with a physiological pH are particularly indicated in patients in whom solutions based on lactate buffer only, with a low pH, cause abdominal inflow pain or discomfort.

Contraindications

PHYSIONEAL 35 should not be used in patients with uncorrectable mechanical defects that prevent effective PD or increase the risk of infection, and in patients with documented loss of peritoneal function or extensive adhesions that compromise peritoneal function.

Special warnings and precautions for use

Peritoneal dialysis should be done with caution in patients with:

1) Abdominal conditions, including disruption of the peritoneal membrane and diaphragm by surgery, from congenital anomalies or trauma until healing is complete, abdominal tumors, abdominal wall infection, hernias, fecal fistula, colostomy or iliostomy, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity.

2) Other conditions including recent aortic graft replacement and severe pulmonary disease.

Encapsulating Peritoneal Sclerosis (EPS) is considered to be a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including some patients using PHYSIONEAL 35 as part of their PD therapy.

If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broadspectrum antibiotics may be indicated.

Patients with elevated lactate levels should use lactate-containing peritoneal dialysis solutions with caution. It is recommended that patients with conditions known to increase the risk of lactic acidosis [e.g., acute renal failure, inborn errors of metabolism, treatment with drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)] must be monitored for occurrence of lactic acidosis before the start of treatment and during treatment with lactate-based peritoneal dialysis solutions.

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. Serum potassium levels should be monitored carefully in patients treated with cardiac glycosides.

Safety and effectiveness in pediatric patients has not been established.

An accurate fluid balance record must be kept and the body weight of the patient must carefully be monitored

Physioneal Continued

to avoid over- or underhydration with severe consequences including congestive heart failure, volume depletion and shock.

In patients with plasma bicarbonate level above 30 mmol/l, the risk of possible metabolic alkalosis should be weighed against the benefits of treatment with this product.

Protein, amino acids, water soluble vitamins and other medicines may be lost during peritoneal dialysis and may require replacement.

Overinfusion of PHYSIONEAL 35 solutions into the peritoneal cavity may be characterized by abdominal distension/abdominal pain and/or shortness of breath.

Treatment of PHYSIONEAL 35 overinfusion is to drain the solution from the peritoneal cavity.

Excessive use of PHYSIONEAL 35 peritoneal dialysis solution with a higher dextrose (glucose) during a peritoneal dialysis treatment may result in excessive removal of water from the patient.

Potassium is omitted from PHYSIONEAL 35 solutions due to the risk of hyperkalemia. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/l) may be indicated to prevent severe hypokalemia and should be made after careful evaluation of serum and total body potassium, only under the direction of a physician.

Serum electrolyte concentrations (particularly bicarbonate, potassium, magnesium, calcium and phosphate), blood chemistry (including parathyroid hormone and lipid parameters) and haematological parameters should be monitored periodically.

In patients with diabetes, blood glucose levels should be monitored and the dosage of insulin or other treatment for hyperglycaemia should be adjusted.

Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis.

Patients must be instructed to open both the long and the short seals prior to infusion. If only the short SafetyMoon seal opens, infusion of the unmixed solution can cause abdominal pain, hypernatremia and severe metabolic alkalosis. In case of infusion of unmixed solution, the patient should immediately drain the solution and use a newly mixed bag.

Pregnancy and lactation

There is no clinical experience with PHYSIONEAL 35 during pregnancy and lactation. No data are available from animal studies. The risk-benefit must be assessed.

Undesirable effects

Adverse reactions (occurring in 1% of patients or more) from the clinical trials and post marketing are listed below.

The adverse drug reactions listed in this section are given following the recommended frequency convention: very common: ≥10%; common: ≥1% and <10%; uncommon: ≥0.1% and <1%; very rare: <0.01%, not known (cannot be estimated from available data).

Commonly Adverse Reaction are: Alkalosis (Physioneal 40 only) Hypokalaemia, Fluid retention, Hypercalcaemia, Hypertension, Peritonitis, Oedema, Asthenia, Weight increased.

Uncommon Adverse Reaction are: Hypervolaemia, Anorexia, Dehydration, Hyperglycaemia, Lactic Acidosis, Insomia, Dizziness, Headache, Hypotension, Dyspnoea, Cough, Peritoneal membrane failure, Abdominal Pain, Dyspepsia, Flatulence, Nausea, Chills, Facial Oedema, Hernia, Malaise, Thirst, PCO_2 increased.

Not known Adverse Reaction are: Pyrexia, Musculoskeletal pain, Angiodema, Rash, Sclerosing encapsulating peritonitis, Cloudy peritoneal effluent, Eosinophilia.

Other undesirable effects of peritoneal dialysis related to the procedure: bacterial peritonitis, catheter site infection, and catheter related complication.

For posology, incompatibilities, interactions, overdosage, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription.

August 2013

Prescribing Information

nutrineal

Abbreviated summary of product characteristics

This abbreviated summary of product characteristics is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet.

NAME OF THE MEDICINAL PRODUCTS

Nutrineal PD4 1.1% Amino Acids Solution for peritoneal dialysis

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 litre solution contains: Alanine 951 mg/l, Arginine 1071 mg/l, Glycine 510 mg/l, Histidine 714 mg/l, Isoleucine 850 mg/l, Leucine 1020 mg/l, Lysine, HCl 955 mg/l, Methionine 850 mg/l, Phenylalanine 570 mg/l, Proline 595 mg/l, Serine 510 mg/l, Threonine 646 mg/l, Tryptophan 270 mg/l, Tyrosine 300mg/l, Valine 1393 mg/l, Sodium chloride 5380 mg/l, Calcium chloride dihydrate 184 mg/l, Magnesium chloride hexahydrate 51 mg/l and Sodium (S)-lactate solution 4480 mg/l.

Amino Acids 87.16 mmol/l, Na+ 132 mmol/l, Ca++ 1.25 mmol/l, Mg++ 0.25 mmol/l, Cl- 105 mmol/l, C3H5O3- 40 mmol/l.

Osmolarity 365 mOsmol/l

pH at 25°C – 6.6

CLINICAL PARTICULARS

Therapeutic indications

Nutrineal is recommended as non-glucose based peritoneal dialysis solution as part of a peritoneal dialysis regimen for the treatment of chronic renal failure patients. In particular, it is recommended for the malnourished peritoneal dialysis patients.

Contraindications

Nutrineal is contraindicated in patients with: hypersensitivity to the active substances or to any of the excipients listed in section 6.1, serum urea level above 38 mmol/L, uraemic symptoms, metabolic acidosis, inborn errors of amino acid metabolism, severe liver insufficiency, severe hypokalaemia, uncorrectable mechanical defects that prevent effective PD or increase the risk of infection; documented loss of peritoneal function or extensive adhesions that compromise peritoneal function.

Special warnings and precautions for use

Encapsulating peritoneal sclerosis (EPS) Encapsulating peritoneal sclerosis (EPS) is considered to be a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including Nutrineal. Peritonitis If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated. Hypersensitivity If any sign or symptom of a suspected hypersensitivity reaction develop, intraperitoneal administration of Nutrineal should be stopped immediately. Appropriate therapeutic measures should be instituted as clinically indicated. Metabolism of Nutrineal A portion of the amino acids in Nutrineal is converted to metabolic nitrogenous waste, such as urea. If dialysis is insufficient, the additional metabolic waste generated by the use of Nutrineal may lead to the appearance of uraemic symptoms such as anorexia or vomiting. Symptoms can be managed by reduction of the number of Nutrineal exchanges, or discontinuation of Nutrineal or an increased dialysis dose with a non amino acid based solution. Uncompensated metabolic acidosis and hyperammonemia: Particular care is indicated in cases of uncompensated metabolic acidosisand hyperammonemia. Metabolic acidosis and hyperammonemia should be corrected before and during Nutrineal treatment. Use in patients with abdominal conditions Peritoneal dialysis should be done with caution in patients with: 1) abdominal conditions, including disruption of the peritoneal membrane and diaphragm by surgery, from congenital anomalies or trauma until healing is complete, abdominal tumours, abdominal wall infection, hernias, faecal fistula, colostomy or iliostomy, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity; and 2) other conditions including aortic graft placement and severe pulmonary disease. General monitoring Significant losses of medicinal products (including water soluble vitamins) may occur during peritoneal dialysis. Replacement therapy should be provided as necessary. Dietary protein intake should be monitored. Patients should be carefully monitored to avoid over- and underhydration. An accurate fluid balance record should be kept and the patient's body weight monitored. Serum electrolyte concentrations (particularly bicarbonate, potassium, magnesium, calcium and phosphate), blood chemistry (including parathyroid hormone) and haematological parameters should be monitored periodically. Overinfusion: Overinfusion of a peritoneal dialysis solution into the peritoneal cavity may be characterised by abdominal distension/abdominal pain and/or shortness of breath. Treatment of peritoneal dialysis solution overinfusion is to drain the solution from the peritoneal cavity. Addition of Potassium: Potassium is omitted from Nutrineal solutions due to the risk of hyperkalaemia. In situations in which there is a normal serum potassium level or hypokalaemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia and should be made after careful evaluation of serum and total body potassium, only under the direction of a physician. Use in diabetic patients: In diabetic patients, blood glucose levels should be regularly monitored and the dosage of insulin or other treatment for hyperglycaemia should be adjusted.Use in patients with secondary hyperparathyroidism: In patients with secondary hyperparathyroidism, the benefits and risks of the use of dialysis solution with low calcium content should be carefully considered as it might worsen hyperparathyroidism. Paediatric population Safety and effectiveness in paediatric patients has not been established.

Fertility, pregnancy and lactation

Pregnancy: There are no data from the use of Nutrineal in pregnant women. No animal reproductive studies have been performed with Nutrineal (see section 5.3). Nutrineal is not recommended during pregnancy and in women of childbearing potential not using contraception. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing Nutrineal. Lactation: It is unknown whether Nutrineal/ metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Nutrineal therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. Fertility: There are no clinical data on fertility.

Undesirable effects

The adverse reactions within this section represent those that are thought to have an association with Nutrineal or in conjunction with performing the peritoneal dialysis procedure. Undesirables effects which occurred in patients treated with Nutrineal from clinical trials and post marketing are listed below. Frequency is based upon the following scale: Very common (≥1/10); Common (≥1/100 - <1/10), Uncommon (≥1/1,000 - <1/100), Rare (≥1/10,000 - <1/1,000), Very rare (<1/10,000); not known (cannot be estimated from the available data).

Very common undesirable effects: Acidosis, Hypervolaemia, Anorexia, Vomiting, Nausea, Gastritis, Asthenia, Blood urea increased.

Common undesirable effects: Infection, Anaemia, Hypokalaemia, Hypovolaemia, Depression, Abdominal pain, Dyspnoea.

Not known undesirable effects: Hypersensitivity, Sclerosing encapsulating peritonitis, Abdominal discomfort, Peritonitis, Peritoneal cloudy effluent, Pruritis, Angioedema, Pyrexia, Malaise, Peritoneal fluid analysis abnormal Other undesirable effects of peritoneal dialysis related to the procedure: catheter site infection, catheter related complication, hypocalcaemia and peritonitis bacterial. Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

For posology, incompatibilities, interactions, overdosage, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription

May 2016

extraneal

Prescribing information

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NAME OF THE MEDICINAL PRODUCT

EXTRANEAL (Icodextrin 7.5%)
Solution for peritoneal dialysis

QUALITATIVE AND QUANTITATIVE COMPOSITION

A sterile peritoneal dialysis fluid containing Icodextrin at a concentration of 7.5% w/v in an electrolyte solution.

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

The pH of the solution is 5,0 to 6,0

Composition of the solution	Concentration in mmol/l
Sodium Calcium Magnesium Chloride Lactate	133 mmol/L 1.75 mmol/L 0.25 mmol/L 96 mmol/L 40 mmol/L
Theoretical osmolarity	284 (milliosmoles per litre) 301 (milliosmoles per kg)

List of excipients: Water for injections, Sodium Hydroxide or Hydrochloric acid q.s to required pH.

CLINICAL PARTICULARS

Therapeutic Indications

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

Contra-indications

Extraneal should not be used in patients with: a known allergy to starch based polymers/or icodextrin, maltose or isomaltose intolerance, glycogen storage disease, pre-existing severe lactic acidocis, uncorrectable mechanical defects that prevent effective PD or increase the risk of infection or documented loss of peritoneal function or extensive adhesions that compromise peritoneal function.

Special Warnings and Precautions for Use

Patients with diabetes mellitus often need additional insulin in order to maintain glycaemic control during Peritoneal Dialysis (PD). Transfer from glucose based PD solution to Extraneal may necessitate an adjustment of the usual insulin dosage. Initial results show that insulin is minimally absorbed from Extraneal in Clear Flex bags compared with PVC bags, so dosage adjustments may be also necessary and special attention is advised in this situation. Insulin can be administered intraperitoneally. Blood glucose measurement must be done with a glucose specific method to prevent maltose interference. Glucose dehydrogenase pyrroloquinolinequinone (GDH- PQQ) or glucose-dye-oxidoreductase (GDO)-based methods should not be used. Also, the use of some glucose monitors and test strips using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) methodology has resulted in falsely elevated glucose readings due to the presence of maltose. 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. If GDH-PQQ-, GDO- or GDH-FAD-based methods are used, using Extraneal may cause a falsely high glucose reading, which could result in the administration of more insulin than needed. Administration of more insulin than needed has caused hypoglycaemia, which has resulted in loss of consciousness, coma, neurological damage and death. Additionally, falsely elevated blood glucose measurements due to maltose interference may mask true hypoglycaemia and allow it to go untreated with similar consequences. Falsely elevated glucose levels may be measured up to two weeks following cessation of Extraneal (icodextrin) therapy when GDH-PQQ-, GDO- or GDH-FAD-based blood glucose monitors and test strips are used. Because GDH-PQQ-, GDO- or GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using Extraneal (icodextrin) carefully review the product information of the blood glucose testing system, including the information of test strips, to determine if the system is appropriate for use with Extraneal (icodextrin). To avoid improper insulin administration, educate patients to alert health care providers of this interaction, whenever they are admitted to the hospital. Peritoneal dialysis should be done with caution in patients with: 1) abdominal conditions, including disruption of the peritoneal membrane and diaphragm by surgery, from congenital anomalies or trauma until healing is complete, abdominal tumours, abdominal wall infection, hernias, faecal fistula, colostomy or iliostomy, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity; and 2) other conditions including recent aortic graft replacement and severe pulmonary disease. Encapsulating peritoneal sclerosis (EPS) is considered to be a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including some patients using Extraneal as part of their PD therapy. Infrequently, fatal outcomes have been reported with Extraneal. Patients with conditions known to increase the risk of lactic acidosis (e.g. severe hypotension, sepsis, acute renal failure, inborn errors of metabolism, treatment with drugs such as metformin and nucleoside/ nucleotide reverse transcriptase inhibitors (NRTIs)) should be monitored for occurrence of lactic acidosis before the start of treatment and during treatment with lactate-based peritoneal dialysis solutions. When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the dialysis treatment and therapy directed at other existing illnesses. Serum potassium levels should be monitored carefully in patients treated with cardiac glycosides. Peritoneal reactions, including abdominal pain, cloudy effluents with or without bacteria (aseptic peritonitis) have been associated with Extraneal. In case of peritoneal reactions, the patient should keep the icodextrin drained fluid bag along with its batch number, and contact the medical team for analysis of the drained fluid bag. The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of infection or aseptic peritonitis. Patients should be asked to inform their physician if this occurs and appropriate microbiological samples should be drawn. The initiation of antibiotic treatment should be a clinical decision based on whether or not infection is suspected. If other possible reasons for cloudy fluid have been excluded, Extraneal should be stopped and the result of this action evaluated. If Extraneal is stopped and the fluid becomes clear afterwards, Extraneal should not be reintroduced unless under close supervision. If by re-challenging with Extraneal, the cloudy fluid recurs then this patient should not be prescribed Extraneal again. Alternative peritoneal dialysis therapy should be initiated and the patient should be kept under close supervision. If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broadspectrum antibiotics may be indicated. Rarely, serious hypersensitivity reactions to Extraneal have been reported such as toxic epidermal necrolysis, angioedema, erythema multiforme and vasculitis. Anaphylactic/anaphylactoid reactions may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Extraneal is not recommended in patients with acute renal failure. Protein, amino acids, water-soluble vitamins and other medicines may be lost during peritoneal dialysis and may require replacement. Patients should be carefully monitored to avoid overhydration or underhydration. Enhanced ultra-filtration, particularly in elderly patients, may lead to dehydration, resulting in hypotension and possibly neurological symptoms. An accurate fluid balance record should be kept and the patient's body weight monitored. Overinfusion of an Extraneal volume into the peritoneal cavity may be characterised by abdominal distension, feeling of fullness and/ or shortness of breath. Treatment of Extraneal overinfusion is to drain Extraneal from the peritoneal cavity. In common with other peritoneal dialysis fluids, Icodextrin should be used with caution, after careful evaluation of its potential risks and benefits, in patients with conditions which preclude normal nutrition, with impaired respiratory function or with potassium deficiency. Fluid, haematology, blood chemistry, and electrolyte concentrations should be monitored periodically, including magnesium and bicarbonate. If serum magnesium levels are low, oral magnesium supplements or peritoneal dialysis solutions containing higher magnesium concentrations may be used. A decrease in the serum sodium and chloride level has been observed in some patients. Though these decreases have been regarded as clinically non-significant, it is recommended that serum electrolyte levels are monitored regularly. A decrease in serum amylase levels has also been noticed as a common finding in PD patients on long term treatment. The decrease has not been reported to be accompanied with any side effects. However, it is not known whether subnormal amylase level may mask the rise in serum amylase, commonly seen during acute pancreatitis. An increase in serum alkaline phosphatase of approximately 20 IU/L was seen during clinical trials. There were individual cases where increased alkaline phosphatase was associated with elevated SGOT- (ASAT-) levels.

Paediatric population: Extraneal is not recommended in children

Pregnancy and Lactation

Pregnancy: There are no or limited amount of data from the use of Extraneal in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. In pregnant women or women of childbearing potential the benefit/risk should be assessed before using the product. Breastfeeding It is unknown whether Extraneal metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Extraneal therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. Fertility: There are no clinical data on fertility.

Undesirable Effects

Undesirable effects which occurred in patients with Extraneal from the clinical trials are:

Common undesirable effects: Dehydration, Hypovolaemia, Dizziness, Headache, Tinnitus, Hypotension, Hypertension, Abdominal Pain, Rash (including macular, papular, erythematous), Pruritus, Skin exfoliation, Oedema peripheral, Asthenia.

Uncommon undesirable effects: Flu syndrome, Furuncle, Anaemia, Leukocytosis, Eosinophilia, Hypoglycaemia, Hyponatraemia, Hyperglycaemia, Hypervolaemia, Anorexia, Hypochloraemia, Hypomagnesaemia, Hypoproteinaemia, Thinking Abnormal, Anxiety, Nervousness, Paraesthesia, Hyperkynesia, Ageusia, Cardiovascular disorder, Tachycardia, Orthostatic hypotension, Pulmonary oedema, Dyspnoea, Cough, Hiccups, Ileus, Peritonitis, Bloody peritoneal effluent, Diarrhoea, Gastric ulcer, Gastritis, Vomiting, Constipation, Dyspepsia, Nausea, Dry mouth, Flatulence, Urticaria, Dermatitis bullous, Psoriasis, Skin ulcer, Eczema, Nail disorder, Dry skin, Skin discolouration, Bone pain , Muscle spasms , Myalgia , Neck pain, Renal pain, Chest pain, Face oedema, Oedema, Pain, Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood alkaline phosphatase increased, Liver function test abnormal, Weight decreased, Weight increased

Not known undesirable effects: Thrombocytopenia, Leucopenia, Vasculitis, Hypersensitivity (Hypersensitivity-type reactions have been reported in patients using Extraneal including bronchospasm, hypotension, rash, pruritus and urticaria), Shock hypoglycaemia, Fluid imbalance, Hypoglycaemic coma, Burning sensation,Vision blurred, Bronchospasm, Ascites, Inguinal hernia, Abdominal discomfort, Toxic epidermal necrolysis, Erythema multiform, Angiodema, Urticaria generalised,Toxic skin eruption, Periorbital oedema, Dermatitis (including allergic and contact), Erythema, Blister, Arthralgia, Back pain, Musculoskeletal pain, Pyrexia, Chills, Malaise, Catheter site erythema, Catheter site inflammation, Infusion related reaction (including infusion site pain, instillation site pain), Device interaction (Icodextrin interferes with blood glucose measurement devices).

Other undesirable effects of peritoneal dialysis related to the procedure: fungal peritonitis, bacterial peritonitis, catheter site infection, catheter related infection and catheter related complication. Enhanced ultrafiltration, particularly in the elderly patients, may lead to dehydration, resulting in hypotension, dizziness and possibly neurological symptoms, Hypoglycaemic episodes in diabetic patients, Increase in serum alkaline phosphatases and electrolyte disturbances (e.g. hypokalaemia, hypocalcaemia and hypercalcaemia).

Peritoneal reactions, including abdominal pain, cloudy effluents with or without bacteria, aseptic peritonitis.

Fatigue was often reported spontaneously and in literature as an undesirable effect related to the procedure.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via their national procedure.

For posology, incompabilities, interactions, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription.

April 2016

Homechoice Claria

HOMECHOICE CLARIA APD SYSTEM

THE RELIABILITY YOU EXPECT.

SPECIFICATIONS

Width:	18.4 in / 46.7 cm
Height:	7.6 in / 19.4 cm
Depth:	15.2 in / 38.7 cm
Weight:	29.8 lbs / 13.5 kg
Languages:	38

For safe and proper use of the device, please refer to the Operations Manual and/or prescribing information.

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