Baxter

New **Homechoice Claria** APD System

Designed to change the world of PD from the inside out.

Homechoice Claria

Making possible personal.

Homechoice Claria APD System from Baxter

Delivering the clinic to your patients.

250 million exchanges and counting

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

Now Baxter takes the Homechoice cycler to the next level

The **Homechoice Claria** APD system is integrated with the **Sharesource** connectivity platform, that offers complete, secure data transfer and allows you to manage device programs remotely.

Homechoice Claria

You know the benefits of peritoneal dialysis (PD). Now deliver them to more patients with the Homechoice Claria APD system.

- Patients treated with PD have better early survival than those treated with conventional haemodialysis [2-5]
- PD avoids vascular access and associated morbidity [6]
- Smoother lifestyle transition compared to conventional haemodialysis [7-9]
- Flexibility to travel

Homechoice Claria APD system with the Sharesource platform:

Clinic Benefit	Patient Benefit
Enables remote patient monitoring and device program changes	May allow more patients to receive benefits of APD therapy [9]
May increase confidence to prescribe APD to more patients	

Homechoice Claria APD System: New Features

Capabilities that help you stay focused on direct patient care and send more patients home.

At first glance, the cycler itself may look quite familiar – it's what's inside that makes all the difference.

Sharesource: Remote, cloud-based patient management

- 2-way communication allows clinic to monitor treatment data and adjust device programs remotely
- No need to wait for patients to bring in paper records (manually-recorded flow sheets) – have it all at your fingertips
  - Store up to 4 device programs; when a new device program is needed, it can be pushed to a patient's system
  - Access up to 30 days of treatment data via the dashboard
  - Unlimited access to a patient's treatment data history within reports

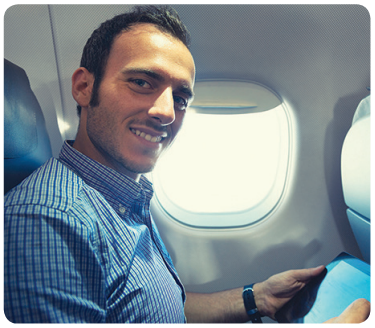
Plus, the Homechoice Claria APD system is:

Inclusive of a wider patient population

- Multiple new languages added (38 total)

Easier for patients to read

- 100% larger screen improves visibility compared to the original **Homechoice** cycler
- Legible from multiple angles
- 2-line display eliminates the need for alternating messages
- Larger font



Homechoice Claria

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
- Allowable ranges and default settings for Tidal Therapies
- Smart Dwells maximize dialysis time
- Built-in logarithms designed to reduce increased intraperitoneal volume (IIPV) and alert the prescriber
- Dedicated nurse menu
- Wide range of programming options and variable configurations allow therapy programs to be tailored to the needs of most patients

Quality of life

- Lightweight, portable and designed for tabletop operation, making it convenient for travel
- Self-correcting alarm management software helps ensure patients get a good night’s sleep

User-friendly display

- Informational displays for patients before, during and after treatments
- Auto-dim screen

Sharesource Connectivity Platform

Stay just a click away from your patients.

Managing your home dialysis patients just got easier with Sharesource, our new web-based connectivity platform. Designed to help you bridge the gap between your clinic and a patient's home, it allows you to remotely monitor their therapy – and ultimately, assists you in delivering better patient care.

Enables more timely care for your patients and more proactive therapy decisions

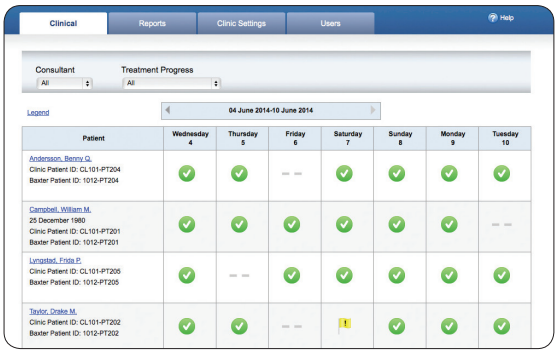
- On-demand access to patient data via web browser allows you to monitor therapies and intervene when needed
- Remotely create and edit device programs to update your patients' therapy
- Set customizable flag alerts within the dashboard to help keep you informed and responsive to your patients' medical needs

May save the clinic time and improve clinic efficiencies

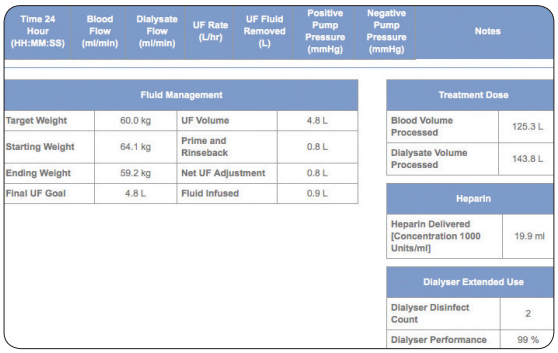
- Ensures accuracy of patient treatment data through automated treatment data collection
- Eliminates manual treatment entry, saving both the clinic and patient administrative work
- Comprehensive treatment reporting allows patient and clinic treatment data to be aggregated for analysis
- Enables remote software upgrades resulting in less hassle for both the clinic and patient

Sharesource

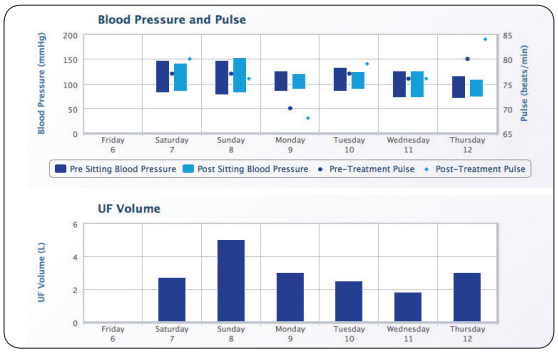
Dashboard



Treatment Details



Patient Trends



Homechoice Claria

Transforming APD from within.

The connectivity of the **Sharesource** platform supports much more than accurate data and proactive therapy decisions – it means patients can feel more secure in performing therapy at home.

Provide more timely patient care – make more proactive therapy decisions

Feature	Benefit
Remotely view patient treatment data from a web browser	On-demand access to data allows you to intervene in a more timely manner – ultimately having more control over your patients' therapies
Remotely create and edit a device program	Update your patients' therapy as needed to provide more timely care – no need to wait for an office visit to intervene
Set clinic level flag alerts	Ensures your clinic focuses on important medical events

Save clinic time – improve efficiencies

Feature	Benefit
Automated patient treatment data collection	Ensures accurate patient treatment data collection; eliminates manual entry of treatment data, reducing administrative burden on patients and clinic
Comprehensive treatment reporting	Allows you to aggregate both patient and clinic treatment data to see the bigger picture more easily; also serves as treatment verification for payers (you have solid proof of treatment for reimbursement purposes)
Remote technical service	Allows Baxter to troubleshoot devices in a more timely manner – fewer device swaps saves time for the patient and clinic
Remote firmware upgrades	Software updates occur without a device swap, eliminating hassle for both the patient and clinic

Service & Support

Here for you.
Here for your patients.

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 is available 24/7 to quickly address patients' needs and alleviate 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

Contact your local Baxter representative to learn which services are available in your market.

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.

Homechoice Claria

Combination for Success

Four 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 and **Sharesource**, the web-based connectivity platform, 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

Sharesource

- Exclusive 2-way communication
- Remote access to patient data
- Proactive device program management
- Remote technical service and firmware upgrades
- Integrated supply ordering*

dianeal extraneal nutrineal physioneal† P.E.N. physioneal · extraneal · nutrineal

- Only non-glucose solution and low glucose therapy combinations
- Only non-glucose solution for the long dwell
- Only non-glucose solution for the short dwell
- Only PD solution proven to improve patient comfort[1,2]

Baxter

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

*Available within customer service portal, which is not available in all markets.

†Not all solutions are available in all markets.

Homechoice Claria APD System

Case Studies*

Name: Karl	**Age:** 65
Life stage: Retired carpenter, married, lives on the outskirts of the city, neither he nor his wife drive	
Diagnosis: Chronic kidney disease, diabetes	
Clinical assessment: Needs to start on dialysis within 1-2 months	

Karl's priorities and concerns:

- Doesn't want to be a burden to his family
- Not familiar with the Internet, computers, new technology
- Wants ample time for family and hobbies
- Has to use public transportation which can be challenging

How the Homechoice Claria APD system addressed Karl's needs:

- Home-based, flexible therapy and treatment schedule alleviates transportation concerns and allows him time to pursue hobbies
- User-friendly **Sharesource** platform further simplifies treatment with automatic data transmission†
- Device programs can be adjusted via the **Sharesource** platform by his nephrologist
- 24/7 access to a technical service helpline further boosts his confidence±

An issue arises:

Karl's nurse discovers red flags after logging into the **Sharesource** platform to review his treatment data: flag indicates Karl finished PD therapy early and performed less cycles than prescribed. She asks that he come in for a checkup to ensure no further issues have arisen.

How Karl's issue is resolved:

At his appointment, Karl's nephrologist reviews Karl and low day time ultrafiltration observed in Sharesource records. For therapy adequacy he prescribes Extraneal (icodextrin). The device program change is made remotely via the **Sharesource** platform, so it's ready for Karl's next therapy session.[11, 12]

Karl feels supported by the clinical staff in their ability to proactively address his needs and he feels more confident in his ability to stay on PD.

* Hypothetical case studies

† Contact your Baxter representative to learn if 24-hour technical service is available in your market.

± After a treatment, the next time the patient powers the machine, the treatment data from the dialysis device automatically uploads to the Sharesource portal and is available for viewing. The time taken will vary, depending on connection speeds and the amount of information transferred.

Homechoice Claria

Name: Sonia	**Age:** 42
Life stage: Highly ambitious journalist, lives in the middle of the city	
Diagnosis: End stage renal disease, glomerulonephritis (unknown, asymptomatic)	
Clinical assessment: Unplanned HD stabilized condition, giving patient time to select treatment modality	

Sonia's priorities and concerns:

- Refuses to let ESRD compromise her career and social life
- Wants to help manage her own therapy
- Wants to maintain her privacy
- Highly active lifestyle that includes traveling

Why the Homechoice Claria APD system?

Sonia and the renal unit team decide that she should start APD with the **Homechoice Claria** system, equipped with the **Sharesource** platform, as it met a number of her lifestyle concerns.

How the Homechoice Claria APD system addressed Sonia's needs:

- Flexible therapy schedule
- Accommodates travel (by design and via support)
- Treatment conducted privately within Sonia's home (or hotel room when traveling)
- The **Sharesource** platform allows her nephrologist and PD nurse to access her treatment data and make device program adjustments remotely
- Baxter Travel Club can assist Sonia with the logistics of travel to ensure her APD supplies are delivered to her destination‡

‡Contact your Baxter representative to learn if the Baxter Travel Club is available in your market.

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

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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

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nutrineal

Abbreviated Prescribing Information

Nutrineal PD4 Clear-Flex and Nutrineal PD4, solution for peritoneal dialysis

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NAME OF THE MEDICINAL PRODUCTS

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

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.

Excipients: Hydrochloric acid, concentrated (pH adjuster) and Water for Injections.

CLINICAL PARTICULARS

Therapeutic indications

Nutrineal is recommended as a 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 should not be used:

- In patients with hypersensitivity to any amino acids in the product or to any of the excipients.
- In patients with serum urea level above 38 mmol/L, in cases of uraemic symptoms, metabolic acidosis, inborn errors of amino acid metabolism, liver insufficiency and 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 warning and precautions for use

- 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.
- 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.

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.

- Metabolic acidosis should be corrected before and during Nutrineal treatment.
- Safety and effectiveness in paediatric patients has not been established.
- 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.
- 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 or colostomy, 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.
- Overinfusion of a peritoneal dialysis solution into the peritoneal cavity may be characterized 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.
- 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.
- Potassium is omitted from Nutrineal 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 haematological parameters should be monitored periodically.
- In diabetic patients, blood glucose levels should be regularly monitored and the dosage of insulin or other treatment for hyperglycaemia should be adjusted.
- 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 uremic 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.
- In patients with secondary hyperparathyroidism, the benefits and risks of the use of dialysis solution with a low calcium content should be carefully considered as it might worsen hyperparathyroidism.

Pregnancy and lactation

There are no clinical data on exposed pregnancies and lactation, and no animal studies are available. Nutrineal should not be used during pregnancy or lactation unless clearly necessary.

Undesirable effects

Undesirable 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).

Very commonly reported undesirable effects which occurred in patients treated with Nutrineal are: Acidosis, Hypervolemia, Anorexia, Gastritis, Asthenia, Blood urea increased, Nausea and Vomiting.

Common undesirable effects which occurred in patients treated with Nutrineal are: Infection, Anemia, Hypokalemia, Hypovolemia, Depression, Dyspnea, Abdominal pain.

Not known reported undesirable effects which occurred in patients treated with Nutrineal are: Abdominal discomfort, Peritonitis, Peritoneal Cloudy effluent, Peritoneal fluid analysis abnormal, Pyrexia, Malaise, Pruritis, Hypersensitivity, Angioedema, Sclerosing encapsulating peritonitis.

Undesirable effects of peritoneal dialysis related to the procedure include: Catheter site infection, Catheter related complication, hypocalcaemia and peritonitis bacterial.

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

Medicinal product subject to medical prescription.

August 2013

Prescribing Information

extraneal

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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 to 6

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
osmolarity	284 (milliosmoles per litre)

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 a continuous ambulatory peritoneal dialysis (CAPD) or 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 CAPD therapy in such patients.

Contraindications

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. 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 that 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 acidocis [e.g., 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 (see section 4.8). In case of peritoneal reactions, the patient should keep the icodextrin drained fluid bag along with it's 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. If a serious reaction is suspected, discontinue Extraneal and institute appropriate treatment as clinically indicated. Extraneal is not recommended in children or 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 over or under hydration. 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 release the EXTRANEAL from the peritoneal cavity by drainage of the EXTRANEAL volume contained within 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 levels.

Pregnancy and Lactation

Animal studies on the effects of icodextrin are insufficient with respect to effects on embryonal/foetal development and lactation.There are no adequate data from the use of Extraneal in pregnant women. Extraneal should not be used during pregnancy or while breastfeeding unless clearly necessary. Women of childbearing potential should be treated with Extraneal only when adequate contraceptive precautions have been taken.

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.

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

Medicinal product subject to medical prescription.

July 2011

Homechoice Claria

dianeal

Abbreviated Prescribing Information

Dianeal PD4 (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

Dianeal PD4 Glucose 1.36% w/v /13.6mg/ml

Dianeal PD4 Glucose 2.27% w/v /22.7mg/ml

Dianeal PD4 Glucose 3.86% w/v /38.6mg/ml

Qualitative and quantitative composition

Dianeal PD4 Glucose 1.36% w/v / 13.6mg/ml Dianeal PD4 Glucose 2.27% w/v / 22.7mg/ml Dianeal PD4 Glucose 3.86% w/v / 38.6mg/ml Each 1 litre contains		mmol per litre (approx.)
Glucose Monohydrate equivalent to Anhydrous Glucose	15.0 or 25.0 or 42.5 g 13.6 or 22.7 or 38.6 g	Sodium 132 Calcium 1.25 Magnesium 0.25
Sodium Chloride	5.38 g	Chloride 95
Sodium Lactate	4.48 g	Lactate 40
Calcium Chloride	184 mg	mOsm per litre 344 or 395 or 483
Magnesium Chloride	51 mg	
Water for Injections to	100% w/v	

Therapeutic indications

Dianeal PD4 is indicated whenever peritoneal dialysis is employed, including: Acute and chronic renal failure; Severe water retention; Electrolyte disorders; Drug intoxication, when a more adequate therapeutic alternative is not available.

Dianeal PD4 is particularly useful for the control of serum calcium and phosphate levels in renal failure patients receiving calcium or magnesium-containing phosphate binders.

Contraindications

DIANEAL is contraindicated in patients with: pre-existing severe lactic acidosis, 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:

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 DIANEAL PD4 as part of their PD therapy. Infrequently, fatal outcomes of EPS have been reported with DIANEAL PD4.

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 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)] 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, calcium and magnesium levels should be monitored carefully in patients treated with cardiac glycosides.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over- or under hydration with severe consequences including congestive heart failure, volume depletion and shock.

Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Patients receiving low calcium solution should have their calcium levels monitored for the development of hypocalcaemia or worsening of hypercalcaemia. In these circumstances, adjustments to the dosage of the phosphate binders and/or vitamin D analogs, and/or calcimimetics should be considered by the physician.

The use of 5 or 6 litres of solution in a single CAPD or APD exchange is not recommended due to potential for overinfusion.

Overinfusion of DIANEAL PD4 solutions into the peritoneal cavity may be characterised by abdominal distension/ abdominal pain and/or shortness of breath.

Treatment of DIANEAL PD4 overinfusion is to drain the solution from the peritoneal cavity.

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

Excessive use of DIANEAL PD4 peritoneal dialysis solution with a higher glucose concentration during a peritoneal dialysis treatment may result in excessive removal of water from the patient.

Potassium is omitted from DIANEAL PD4 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 hypokalaemia 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.

Diabetics require careful monitoring of blood-glucose levels during and following dialysis with glucose-containing solutions. The dosage of insulin or other treatment for hyperglycaemia should be adjusted.

Fertility, pregnancy and lactation

There is no clinical experience with DIANEAL PD1 during pregnancy and lactation. No data are available from animal studies. When assessing peritoneal dialysis as a mode of therapy during advanced pregnancy, the benefits to the patient must be weighed against the possible complications.

Undesirable effects

Adverse reactions from post marketing experience 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).

Not known Adverse Reaction are: Hypokalaemia, Fluid retention, Hypervoloaemia, Hypovolaemia, Hyponatraemia, Dehydration, Hypochloraemia, Hypertension, Hypotension, Dyspnoea, Sclerosing encapsulating peritonitis, Cloudy peritoneal effluent, Vomiting, Diarrhoea, Nausea, Constipation, Abdominal pain, Abdominal discomfort, Abdominal distension, Stevens-Johnson syndrome, Urticaria, Rash (including pruritic, erythematous and generalised, Pruritus, Myalgia, Muscle Spasms, Muskuloskeletal pain, Generalised oedema, Pyrexia, Malaise, Infusion site pain.

Other undesirable effects of peritoneal dialysis related to the procedure: fungal peritonitis, bacterial peritonitis, catheter related 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

Homechoice Claria

New **Homechoice Claria** APD System

The reliability you expect. The cutting-edge technology you've never had before.

Specifications:

Width – 46.7 cm

Depth – 38.7 cm

Height – 19.4 cm

Weight – 13.5 kg

Languages – 38

Sharesource

[1] Data on file. Baxter International Inc., Deerfield, IL.

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