New Homechoice Claria APD System

Designed to change the world of PD from the inside out.
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.
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 haemodialysis²-⁵
- PD avoids vascular access and associated morbidity⁶
- Smoother lifestyle transition compared to conventional haemodialysis⁷-⁹
- Flexibility to travel

<table>
<thead>
<tr>
<th>Homechoice Claria APD system with the Sharesource platform:</th>
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<tbody>
<tr>
<td><strong>Clinic Benefit</strong></td>
</tr>
<tr>
<td>Enables remote patient monitoring and device program changes</td>
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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
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 (IPV) 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
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
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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Benefit</th>
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</thead>
<tbody>
<tr>
<td>Remotely view patient treatment data from a web browser</td>
<td>On-demand access to data allows you to intervene in a more timely manner – ultimately having more control over your patients’ therapies</td>
</tr>
<tr>
<td>Remotely create and edit a device program</td>
<td>Update your patients’ therapy as needed to provide more timely care – no need to wait for an office visit to intervene</td>
</tr>
<tr>
<td>Set clinic level flag alerts</td>
<td>Ensures your clinic focuses on important medical events</td>
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### Save clinic time – improve efficiencies

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<tr>
<th>Feature</th>
<th>Benefit</th>
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<tr>
<td>Automated patient treatment data collection</td>
<td>Ensures accurate patient treatment data collection; eliminates manual entry of treatment data, reducing administrative burden on patients and clinic</td>
</tr>
<tr>
<td>Comprehensive treatment reporting</td>
<td>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)</td>
</tr>
<tr>
<td>Remote technical service</td>
<td>Allows Baxter to troubleshoot devices in a more timely manner – fewer device swaps saves time for the patient and clinic</td>
</tr>
<tr>
<td>Remote firmware upgrades</td>
<td>Software updates occur without a device swap, eliminating hassle for both the patient and clinic</td>
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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

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.

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

<table>
<thead>
<tr>
<th><strong>Combination for Success</strong></th>
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<tr>
<td><strong>Homechoice Claria</strong></td>
</tr>
<tr>
<td>• 38 languages</td>
</tr>
<tr>
<td>• Pediatric capability</td>
</tr>
<tr>
<td>• Improved display visibility</td>
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<table>
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<th><strong>Sharesource</strong></th>
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<tbody>
<tr>
<td>• Exclusive 2-way communication</td>
</tr>
<tr>
<td>• Remote access to patient data</td>
</tr>
<tr>
<td>• Proactive device program management</td>
</tr>
<tr>
<td>• Remote technical service and firmware upgrades</td>
</tr>
<tr>
<td>• Integrated supply ordering*</td>
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<table>
<thead>
<tr>
<th><strong>Mckesson</strong></th>
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<tbody>
<tr>
<td>• Only non-glucose solution and low glucose therapy combinations</td>
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<tr>
<td>• Only non-glucose solution for the long dwell</td>
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<tr>
<td>• Only non-glucose solution for the short dwell</td>
</tr>
<tr>
<td>• Only PD solution proven to improve patient comfort†</td>
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<tr>
<th><strong>Baxter</strong></th>
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<tbody>
<tr>
<td>• With our comprehensive service and support, you and your patients have access to a network of knowledgeable Baxter experts at every therapy touchpoint</td>
</tr>
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</table>

*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*

<table>
<thead>
<tr>
<th>Name: Karl</th>
<th>Age: 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life stage:</td>
<td>Retired carpenter, married, lives on the outskirts of the city, neither he nor his wife drive</td>
</tr>
<tr>
<td>Diagnosis:</td>
<td>Chronic kidney disease, diabetes</td>
</tr>
<tr>
<td>Clinical assessment:</td>
<td>Needs to start on dialysis within 1-2 months</td>
</tr>
</tbody>
</table>

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.1,12

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.
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

¹Contact 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

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 bicarbonate/lactate based peritoneal dialysis solutions with a physiological pH are particularly indicated in patients where sodium or potassium levels should be monitored carefully in patients treated with cardiac glycosides.

safety and effectiveness in pediatric patients has not been established.

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 discomfort.

• drug intoxication with dialysable substances, when a more adequate therapeutic alternative is not available.

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 fistostomy, frequent episodes of diverticulitis, inflammatory or ischemic bowel disease, large polyposic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or infra-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 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), broad-spectrum 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.

composition of the final solution after mixing in mmol/l

physioneal 35:

<table>
<thead>
<tr>
<th>Glucose 1.36% w/v / 13.6 mg/ml</th>
<th>Glucose 2.27% w/v / 22.7 mg/ml</th>
<th>Glucose 3.86% w/v / 38.6 mg/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>75.5 mmol/l</td>
<td>126 mmol/l</td>
<td>214 mmol/l</td>
</tr>
<tr>
<td>Na⁺ 132 mmol/l</td>
<td>132 mmol/l</td>
<td>132 mmol/l</td>
</tr>
<tr>
<td>Ca²⁺ 25 mmol/l</td>
<td>25 mmol/l</td>
<td>25 mmol/l</td>
</tr>
<tr>
<td>Mg²⁺ 0.25 mmol/l</td>
<td>0.25 mmol/l</td>
<td>0.25 mmol/l</td>
</tr>
<tr>
<td>Cl⁻ 101 mmol/l</td>
<td>101 mmol/l</td>
<td>101 mmol/l</td>
</tr>
<tr>
<td>HCO₃⁻ 25 mmol/l</td>
<td>25 mmol/l</td>
<td>25 mmol/l</td>
</tr>
<tr>
<td>C₂H₅O₃ 10 mmol/l</td>
<td>10 mmol/l</td>
<td>10 mmol/l</td>
</tr>
<tr>
<td>Osmolarity 345 mOsmol/l</td>
<td>396 mOsmol/l</td>
<td>484 mOsmol/l</td>
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</table>

physioneal 40:

<table>
<thead>
<tr>
<th>Glucose 1.36% w/v / 13.6 mg/ml</th>
<th>Glucose 2.27% w/v / 22.7 mg/ml</th>
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<tbody>
<tr>
<td>76.5 mmol/l</td>
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<td>1.25 mmol/l</td>
<td>1.25 mmol/l</td>
</tr>
<tr>
<td>Mg²⁺ 0.25 mmol/l</td>
<td>0.25 mmol/l</td>
<td>0.25 mmol/l</td>
</tr>
<tr>
<td>Cl⁻ 95 mmol/l</td>
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<td>95 mmol/l</td>
</tr>
<tr>
<td>HCO₃⁻ 25 mmol/l</td>
<td>25 mmol/l</td>
<td>25 mmol/l</td>
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<td>Osmolarity 344 mOsmol/l</td>
<td>395 mOsmol/l</td>
<td>483 mOsmol/l</td>
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</table>

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.
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. Overdilution 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 overdilution is to drain the solution from the peritoneal cavity. Excessive use of PHYSIONEAL 35 peritoneal dialysis solution with a higher dextrose (glucose) concentration 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 the plasma potassium level or hyperkalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hyperkalemia 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 haemostatological parameters should be monitored. 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: <0.1%. known (cannot be estimated from available data).

Commonly Adverse Reaction are: Hypokalaemia, Fluid retention, Hypocalcaemia, Hypertension, Peritonitis, Oedema, Anaemia, Weight increased.

Uncommon Adverse Reaction are: Hyperglycaemia, Anorexia, Dizziness, Hypoglycaemia, Lactic Acidosis, Insomnia, Dizziness, Headache, Hypotension, Dyspnoea, Cough, Peritoneal membrane failure, Abdominal Pain, Dyspepsia, Flatulence, Nasal Obstruction, Facial Oedema, Hiccups, Malaise, Thirst, PCO2 increased.

Not known Adverse Reaction are: Pyrexia, Musculoskeletal pain, Angina, Rashes, Sciering, encapsulating peritonitis, Cloudy peritoneal effluent, Essentiophili.

Other undesirable effects of peritoneal dialysis related to the procedure: bacterial peritonitis, catheter site infection, and catheter related complication. For pregnancy, incompatibilities, interactions, pharmacological properties and pharmaceutical particulars, please refer to the full SPC. Medicinal product subject to medical prescription. August 2013

Abbreviated Prescribing Information Nutrineal PD4 Clear-Flex and Nutrineal 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 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, Arginine 1071 mg, Glycine 510 mg, Histidine 714 mg, Isoleucine 850 mg, Leucine 1020 mg, Lysine, HCL 951 mg, Methionine 850 mg, Phenylalanine 570 mg, Proline 595 mg, Serine 510 mg, Threonine 646 mg, Tyrosine 270 mg, Tyrosine 300 mg, Valine 1293 mg, Sodium chloride 5300 mg, Calcium chloride dihydrate 144 mg, Magnesium chloride hexahydrate 51 mg and Sodium (S)-lactate solution 4480 mg.

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 levels above 38 mmol/L in cases of uraemic symptoms, metabolic acidosis, inborn errors of amino acid metabolism, liver insufficiency and severe hyperkalemia.
- 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 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, focal fistulae 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.

- Treatment of peritoneal dialysis solution overdilution 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 hyperkalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hyperkalemia 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) 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 uraemic symptoms such as anaemia 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 (≥0.1% and <1%), Very rare: <0.1%, known (cannot be estimated from available data).

Very commonly reported undesirable effects which occurred in patients treated with Nutrineal are: Acidosis, Hypoponemia, Anorexia, Gastritis, Atherothrombosis, Blood urea increased, Naussae and vomiting. Common undesirable effects which occurred in patients treated with Nutrineal are: Infection, Anaemia, Hypoponemia, Hypoponemia, Depression, Dyspnoea, 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, Angina, Rashes, Sciering, encapsulating peritonitis. Undesirable effects of peritoneal dialysis related to the procedure include: Catheter site infection, Catheter related complication, Hypoponemia and peritonitis bacterial. For pregnancy, incompatibilities, interactions, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription. August 2013
extraneal

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 the original summary of product characteristics (SPC) prior to therapy. The SPC contains all the necessary information on prescribing, contraindications, warnings, precautions, and special hazards. This product should not be used in patients with a known allergy to starch based polymers/or icodextrin, maltose or isomaltose intolerance, glycerin storage disease, pre-existing severe lactic acidosis, 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

Extraneal should not be used in patients with: a known allergy to starch based polymers/or icodextrin, maltose or isomaltose intolerance, glycerin storage disease, pre-existing severe lactic acidosis, 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.

Composition of the solution

Concentration in mmol/L

Sodium
133 mmol/L
Calcium
1.76 mmol/L
Magnesium
0.25 mmol/L
Chloride
96 mmol/L
Lactate
40 mmol/L

osmolality

284 (milliosmoles per litre)

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

Common undesirable effects: Dehydration, Hypovolaemia, Dizziness, Headache, Tinnitus, Hypotension, Abdominal Pain, Rash (including macular, papular, erythematous), Pruritus, Skin exfoliation, Diarrhoea, Seizures, Anaesthesia, Uncommon undesirable effects: Flu syndrome, Fumurice, Anoxemia, Leucocytosis, Eosinophilia, Hypoglycaemia, Hyperpyrexia, Hypocapnia, Hypoglycaemia, Anoxemia, Hypochloroemia, Hypomagnesaemia, Hypoglycaemia, Hypoglycaemia, Hypocholesterolaemia, Hypocholesterolaemia, Hypocholesterolaemia, Nervousness, Parasthesias, Hypokalaemia, Agranulocytosis, Thrombocytopenia, Leucopenia, Vasculitis, Hypersensitivity (Hypersensitivity-

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 or under hydration. Enhanced ultrafiltration, 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 overinflation is to release the EXTRANEAL from the peritoneal cavity volu...
Dianeal PD4 (Solution for peritoneal dialysis)

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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 ileostomy, 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 treatment. 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), broad-spectrum antibiotics may be indicated.

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

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 / 38.8mg/ml

Each 1 litre contains mmol per litre (approx.)

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Glucose Monohydrate</td>
<td>15.0 or 25.0 or 42.5 g</td>
</tr>
<tr>
<td>Anhydrous Glucose</td>
<td>13.6 or 22.7 or 38.6 g</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>5.38 g</td>
</tr>
<tr>
<td>Sodium Lactate</td>
<td>4.48 g</td>
</tr>
<tr>
<td>Calcium Chloride</td>
<td>1.94 mg</td>
</tr>
<tr>
<td>Magnesium Chloride</td>
<td>51 mg</td>
</tr>
<tr>
<td>Water for Injections</td>
<td>100% w/v</td>
</tr>
<tr>
<td>Sodium</td>
<td>132</td>
</tr>
<tr>
<td>Calcium</td>
<td>1.25</td>
</tr>
<tr>
<td>Magnesium</td>
<td>0.25</td>
</tr>
<tr>
<td>Chloride</td>
<td>95</td>
</tr>
<tr>
<td>Lactate</td>
<td>40</td>
</tr>
</tbody>
</table>

Non-proprietary names:

Calcium Chloride
Sodium Lactate
Anhydrous Glucose
Glucose Monohydrate
Sodium Chloride
Magnesium Chloride
Water for Injections

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
New Homechoice Claria APD System

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

Specifications:

<table>
<thead>
<tr>
<th>Width</th>
<th>Depth</th>
<th>Height</th>
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<th>Languages</th>
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</thead>
<tbody>
<tr>
<td>46.7 cm</td>
<td>38.7 cm</td>
<td>19.4 cm</td>
<td>13.5 kg</td>
<td>38</td>
</tr>
</tbody>
</table>

Data on file, Baxter International Inc., Deerfield, IL.


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