HOMECHOICE CLARIA APD SYSTEM

DESIGNED TO ENHANCE
APD THERAPY
FROM THE INSIDE OUT
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. Today, over 75,000 patients worldwide use it on a daily basis.

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.

**THE OPTIMAL SOLUTION FOR THE LONG DWELL**

*Glucose-free solution*
- Provides superior water and sodium removal compared to a 2.27% glucose solution
- Improves fluid balance
- Reduces carbohydrate absorption
- Preserves the peritoneal membrane transport status
- Improves small and middle molecule clearance
- Clinically proven treatment benefits and safety in combination with PD solutions from Baxter

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

**THE ONLY NON-GLUCOSE SOLUTION FOR THE SHORT DWELL**

*Glucose-free, effective PD solution*
- Reduces glucose exposure from the first day of treatment
- More biocompatible solution
- Clinically proven treatment benefits and safety in combination with PD solutions from Baxter

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

**SOLUTION FOR A NATURAL MEMBRANE**

Improve patient comfort — patients reportedly feel better
- Maintain acid-base balance
- Important biocompatible attributes
- Physiologic pH
- Physiologic bicarbonate levels
- Physiologic pCO2
- Low levels of GDPs

Clinically proven treatment benefits and safety in combination with Extraneal and Nutrineal

**Physioneal** is a PD solution that improves patients’ well-being and maintains acid-base balance.
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 was 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
• Allowable ranges and default settings for Tidal Therapies
• Smart Dwells helps to maximise 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

User-friendly display
• A 2-line OLED screen that eliminates alternating messages and improves the user experience
• Screen design upgraded to improve visibility from multiple angles
• Screen size now 100% larger than international display
• 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
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.

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

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.

COMBINATION FOR SUCCESS

- 38 languages
- Pediatric capability
- Improved display visibility

- 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
- Most widely used osmotic agent in PD

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

HERE FOR YOU
HERE FOR YOUR PATIENTS

*Not all solutions are available in all markets.
Physioneal 35 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.

NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 35 Glucose 2.27% w/v / 22.7 mg/ml Clear-Flex

PHYSIONEAL 35 Glucose 1.36% w/v / 13.6 mg/ml Clear-Flex

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 adhesions that compromise peritoneal function.

Acute and chronic renal failure

Inborn errors of metabolism, treatment with drugs such as metformin and nucleoside/nucleotide analogues (e.g., zidovudine), intestinal obstruction, surgical trauma, burns, and shock, breast feeding, and breast milk consumption, hypocalcaemia, hypophosphataemia, Lactic Acidosis, Insomnia, Dizziness, Headache, Hypotension, Dyspnoea, Cough, Peritoneal membrane failure (Peritonitis, Oedema), Uremic Pericarditis, Fever, Nausea, Cramps, Pulmonary edema, Nursing, Birth, Traumatic brain injury, (cannot be estimated from available data).

Pregnancy and lactation

No data are available. A systematic review concluded that there is no evidence that PHYSIONEAL 35 appears to be associated with an increased risk of congenital malformations when compared to other similar solutions. No data are available on the risk of congenital malformations in infants born to women who received PHYSIONEAL 35 during their pregnancy.

Therefore, please always consult your country-specific SPC or package leaflet.

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 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.

Protein, amino acids, water soluble vitamins and other medicines may be lost during peritoneal dialysis and should be weighed against the benefits of treatment with this product.

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.

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

In patients with plasma bicarbonate level above 30 mmole/L, treatment for hyperglycaemia should be adjusted.

In patients with plasma bicarbonate level above 30 mmole/L, Insulin treatment should be adjusted.

Serum electrolyte concentrations (particularly bicarbonate, potassium, magnesium, calcium and phosphorus) should be monitored periodically.

Serum electrolyte concentrations (particularly bicarbonate, potassium, magnesium, calcium and phosphorus) should be monitored periodically.

Potassium is omitted from PHYSIONEAL 35 solutions due to the risk of hyperkalemia. In situations in which there is an urgent need for potassium treatment, the addition of potassium chloride to a concentration of 15 mmol/L may be made after careful evaluation of serum and body potassium, only under the direction of a physician.

Combination therapy

Patients with elevated lactate levels should use lactate-containing peritoneal dialysis solutions instead of patients using PHYSIONEAL 35 as part of their PD therapy.

When prescribing the solution to be used for an individual patient, consideration should be given to the potential interaction between the drugs and therapy and those drugs administered during peritoneal dialysis.

Concomitant Use

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.

Adverse reactions

Adverse reactions occurring in >1% of patients or 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).


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

For pregnancy, lactation, interactions, overdose, pharmacological properties and pharmacokinetics, please refer to the full SPC.

Prescribing Information
**Prescribing Information**

**Therapeutic Indications**

**Extraneal intradialysis solution** is used as a single use replacement for peritoneal dialysis therapy. **Clinitrol** and **Nutrineal** are different products, but the charts and dose recommendations are similar. This prescriber information and summary of product characteristics (SPC) describes the use of **Clinitrol** only. It is intended as a guide for the user. **Supplementary information** is also provided for **Extraneal intradialysis solution**. The extra dialysate concentration of Clinitrol is 14%, compared with 12% for Extraneal intradialysis solution.

**Extraneal intradialysis solution** is an amino acid-based parenteral solution used as a part of the peritoneal dialysis regimen for the treatment of chronic renal failure in patients. It is recommended for the management of patients with metabolic acidosis and hyperammonemia.

**Care is indicated in cases of uncompensated metabolic acidosis and hyperammonemia. Metabolic acidosis and**

**Special warnings and precautions for use**

**Metabolism of Nutrineal**

A portion of the amino acids in Nutrineal is converted to metabolic nitrogenous waste, including ammonia, and urea. The manufacturing process of Nutrineal includes the conversion of sucrose to dextrose, which can result in the production of an amino acid nitrogen profile that is not ideal for nutritional support. However, the amino acid profile of Nutrineal is designed to meet the metabolic needs of patients with metabolic acidosis and hyperammonemia. Nutrineal is contraindicated in patients with a known hypersensitivity to any of its components or to any sugar or excipients. Nutrineal is also contraindicated in patients with a history of pancreatitis, severe liver disease, or untreated hypothyroidism. Nutrineal is not recommended in patients with acute renal failure.

**Nutrineal PD4 1.1%**

**Amino Acids Solution** for peritoneal dialysis

**CLINICAL PARTICULARS**

**pH at 25°C**

- pH: 5.0 to 6.0

**Composition of the solution**

- Concentration in mmol/l

  - Sodium: 150 mmol/l
  - Chloride: 100 mmol/l

**The pH of the solution is 5.6 to 6.0.**

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- Concentration in mmol/l

  - Sodium: 150 mmol/l
  - Chloride: 100 mmol/l

**The pH of the solution is 5.6 to 6.0.**

**Qualitative and Quantitative Composition**

**Clinitrol**

- A single use replacement for peritoneal dialysis therapy

**Clinitrol** is a single use replacement for peritoneal dialysis therapy. It is used as a single use replacement for peritoneal dialysis therapy. **Clinitrol** and **Nutrineal** are different products, but the charts and dose recommendations are similar. This prescriber information and summary of product characteristics (SPC) describes the use of **Clinitrol** only. It is intended as a guide for the user. **Supplementary information** is also provided for **Extraneal intradialysis solution**. The extra dialysate concentration of Clinitrol is 14%, compared with 12% for Extraneal intradialysis solution.

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**Nutrineal PD4 1.1%**

**Amino Acids Solution** for peritoneal dialysis

**CLINICAL PARTICULARS**

**pH at 25°C**

- pH: 5.0 to 6.0

**Composition of the solution**

- Concentration in mmol/l

  - Sodium: 150 mmol/l
  - Chloride: 100 mmol/l

**The pH of the solution is 5.6 to 6.0.**

**Qualitative and Quantitative Composition**

**Clinitrol**

- A single use replacement for peritoneal dialysis therapy

**Clinitrol** is a single use replacement for peritoneal dialysis therapy. It is used as a single use replacement for peritoneal dialysis therapy. **Clinitrol** and **Nutrineal** are different products, but the charts and dose recommendations are similar. This prescriber information and summary of product characteristics (SPC) describes the use of **Clinitrol** only. It is intended as a guide for the user. **Supplementary information** is also provided for **Extraneal intradialysis solution**. The extra dialysate concentration of Clinitrol is 14%, compared with 12% for Extraneal intradialysis solution.

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References


2. Summary of product characteristics, Extraneal.


11. Summary of Product Characteristics, Nutrineal


16. Schmulwies CG et al. Reduced 1,2-dicarbonyl compounds in bicarbonate/lactate buffered peritoneal dialysis fluids and PD fluids based on glucose polymers or amino acids. Perit Dial Int 2003;23:796-798.


