ABBREVIATED PRESCRIBING INFORMATION

Physioneal 35 Solution for peritoneal dialysis
PHYSIONEAL 35 Clear- Flex, Solution for peritoneal dialysis

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

NAME OF THE MEDICINAL 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,
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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	1.75mmol/l	1.75 mmol/l
Mg^{++}	0.25 mmol/l	0.25mmol/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 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 hydrogen carbonate/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
should not be used in patients with hypersensitivity to the active substances or to any excipients, 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 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 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 solutions into the peritoneal cavity may be characterized by abdominal distension/abdominal pain and/or shortness of breath.
Treatment of PHYSIONEAL overinfusion is to drain the solution from the peritoneal cavity.
Excessive use of PHYSIONEAL 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 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 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.

Reporting of suspected adverse reactions

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

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

Medicinal product subject to medical prescription
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