USER INFORMATION
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PERITONIL® H1
(Peritoneal Dialysis Solution (Lactate) with 1.5% Dextrose)

Composition:

Sodium Chloride BP		5.66 g
Calcium Chloride BP		0.27 g
Magnesium Chloride BP		0.15 g
Sodium Lactate USP		3.92 g
Dextrose Anhydrous BP		15.00 g
Water for Injections BP	to	1000mL

Electrolytes:

The electrolytes of PERITONIL® H1;

Electrolytes	mmol/L	mEq/L
Sodium Ion (Na^+)	132.00	132.00
Calcium Ion (Ca^{++})	1.80	3.60
Magnesium Ion (Mg^{++})	0.75	1.50
Chloride Ion (Cl^-)	102.00	102.00
Bicarbonate Ion (as Lactate)	35.00	35.00

Product Description:

PERITONIL® H1 is a sterile and non-pyrogenic Peritoneal Dialysis Solution.

Pharmacology:

Pharmacodynamics:

For patients with renal failure, peritoneal dialysis is a procedure for removing toxic substances produced by nitrogen metabolism and normally excreted by the kidneys, and for aiding the regulation of fluid and electrolyte as well as acid-base balances.

This procedure is accomplished by administering peritoneal dialysis fluid through a catheter into the peritoneal cavity. Transfer of substances between the dialysis fluid and the patient's peritoneal capillaries is made across the peritoneal membrane according to the principles of osmosis and diffusion. After a few hours of dwell time, the solution is saturated with toxic substances and must be changed with the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated in an attempt to normalise plasma electrolyte concentrations. Nitrogenous waste products, present in high concentrations in the blood, cross the peritoneal membrane into the dialysing fluid. Glucose produces a solution hyperosmolar to the plasma, creating an osmotic gradient that facilitates fluid removal from the plasma to the solution, necessary to compensate for the overhydration observed in chronic renal failure patients.

Pharmacokinetics:

Intraperitoneally administered glucose is absorbed into the blood and metabolised by the usual pathways. For chronic renal disease requiring dialysis and for acute renal failure.

Indications:

Acute renal failure. (e.g. before transfer to Dialysis Centre)
Chronic renal failure. (e.g. temporary dialysis, intermittent to long term dialysis, before diagnostic or surgical procedures)
Acute intoxication. (e.g. of barbiturates, Salicylates, Methanol)
Refractory oedema after therapy. (e.g., cardiac insufficiency)

Recommended Dosage:

Administer in portions of 1-2 liters into the abdominal cavity. The solution to be retained for about 10-15 minutes and then to be drained out. Normally 60-80 liters of dialysate are needed per treatment unless advised otherwise by the attending physician.

Route of Administration: Intraperitoneal Dialysis Fluid

Contraindications:

Abdominal adhesion
Immediately after abdominal surgery, specifically transaction of the retroperitoneum
Pregnancy
Hypercalcaemia
Hyperlactataemia
Hypersensitivity to the active substances or to any of the excipients in this product
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.

Warning and Precautions

Checked for leaks by squeezing the bag. If leaks are found, do not use. If any solid particle, growth or turbidity appears during storage, the product should not be used. The administration of PERITONIL® H1 has to be strictly carried out under aseptic condition. PERITONIL® H1 peritoneal dialysis solutions are intended for intraperitoneal administration only. **Not for intravenous administration**. Do not administer if the solution is discolored, cloudy, contains particulate matter or shows evidence of leakage, if seals are not intact.

• 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 therapy. EPS has been reported in patients using peritoneal dialysis solutions including some patients using PERITONIL® H1 as part of their PD therapy. Infrequently, fatal outcomes of EPS have been reported with PERITONIL® H1.

• 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 the identification of the involved organism(s), broad-spectrum antibiotics may be indicated.

• Solutions containing glucose should be used with caution in patients with a known allergy to corn or corn products. Hypersensitivity reactions such as those due to a corn starch allergy, including anaphylactic / anaphylactoid reactions, may occur. Stop the infusion immediately and drain the solution from the peritoneal cavity if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

• Patients with severe lactic acidosis should not be treated with lactate-based Peritoneal Dialysis Solutions. It is recommended that patients with conditions known to increase the risk of lactic acidosis [e.g., severe hypotension or sepsis that can be associated with acute renal failure, inborn errors of metabolism, treatment with drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)] must be monitored for the 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 hypocalcemia or worsening of hypercalcemia 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.

• Over infusion of PERITONIL® H1 solutions into the peritoneal cavity may be characterised by abdominal distension/abdominal pain and/or shortness of breath.

• Treatment of PERITONIL® H1 over infusion is to drain the solution from the peritoneal cavity.

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

• Excessive use of PERITONIL® H1 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 PERITONIL® H1 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 hematological 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 hyperglycemia should be adjusted.

Interactions with Other Medicaments
No interaction studies have been conducted with PERITONIL® H1. The blood concentration of dialysable drugs may be reduced by Peritoneal Dialysis. Plasma levels of Potassium, Calcium and Magnesium in patients using cardiac glycosides must be carefully monitored, as there is a risk of digitalis intoxication. Potassium supplements may be necessary.

Pregnancy and Lactation:
Pregnancy
There is no or limited amount of data on the use of PERITONIL® H1 in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. PERITONIL® H1 is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breastfeeding
It is unknown whether PERITONIL® H1 metabolites are excreted in human milk.
A risk to the newborns/infants cannot be excluded.
A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from PERITONIL® H1 therapy considering the benefit of breastfeeding for the child and the benefit of therapy for the woman.

Adverse Effects / Undesirable Effect:
The adverse reactions within this section represent those that are thought to have an association with PERITONIL® H1 or in conjunction with performing the peritoneal dialysis procedure. Undesirable effects which occurred in patients treated with PERITONIL® H1 from post-marketing are listed below.

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

System Organ Class	Preferred term	Frequency
Metabolism and Nutritional Disorders	Hypokalemia Fluid retention Hypervolemia Hypovolemia Hyponatremia Dehydration Hypochloremia	Not known
Vascular Disorders	Hypertension Hypotension	Not known
Respiratory, Thoracic, And Mediastinal Disorders	Dyspnea	Not known
Gastrointestinal Disorders	Sclerosing encapsulating peritonitis Peritonitis Peritoneal cloudy effluent Vomiting Diarrhea Nausea Constipation Abdominal pain Abdominal distension Abdominal discomfort	Not known
Skin and Subcutaneous Disorders	Stevens-Johnson syndrome Urticaria Rash (including pruritic, erythematous and generalised) Pruritus	Not known
Musculoskeletal, Connective Tissue Disorders	Myalgia Muscle spasms Musculoskeletal pain	Not known
General Disorders and Administrative Site Conditions	Generalised edema Pyrexia Malaise Infusion site pain	Not known

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

Incompatibilities:
Consult with pharmacist familiar with peritoneal dialysis, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Refer to directions for use accompanying drugs to obtain full information on additives. Some drug additives may be incompatible with PERITONIL® H1.

Addition of Potassium
Potassium is omitted from PERITONIL® H1 solutions because dialysis may be performed to correct hyperkalaemia. In situations where 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. The decision to add potassium chloride should be made by the physician after careful evaluation of serum potassium.

Addition of Insulin
Addition of insulin to PERITONIL® H1 was evaluated in 6 insulin-dependent diabetic patients undergoing CAPD for ESRD. No interference of PERITONIL® H1 with insulin absorption from the peritoneal cavity or with insulin's ability to control blood glucose was observed. Appropriate monitoring of blood glucose should be performed when initiating PERITONIL® H1 in diabetic patients and insulin dosage adjusted if needed.

Addition of Heparin
No human drug interaction studies with heparin were conducted. In vitro studies demonstrated no evidence of incompatibility of heparin with PERITONIL® H1.

Addition of Antibiotics
No formal clinical drug interaction studies have been performed. In vitro studies of the following anti-infectives have demonstrated stability with the product: amphotericin B, ampicillin, azlocillin, cefapirin, cefazolin, cefepime, cefotaxime, ceftazidime, ceftriaxone, ciprofloxacin, clindamycin, cotrimoxazole, deferoxamine, erythromycin, gentamicin, linezolid, mezlocillin, miconazole, moxifloxacin, nafcillin, ofloxacin, penicillin G, piperacillin, teicoplanin, ticarcillin, tobramycin, and vancomycin. However, aminoglycosides should not be mixed with penicillins due to chemical incompatibility.

Overdose and Treatment:
There is potential for overdose resulting in hypervolemia, hypovolemia, electrolyte disturbances or (in diabetic patients) hyperglycemia.

Management of overdose:
Hypervolemia may be managed by using hypertonic peritoneal dialysis solutions and fluid restriction. Hypovolemia may be managed by fluid replacement either orally or intravenously, depending on the degree of dehydration.

Electrolyte disturbances shall be managed according to the specific electrolyte disturbance verified by a blood test. The most probable disturbance, hypokalemia, may be managed by the oral ingestion of potassium or by the addition of potassium chloride in the peritoneal dialysis solution prescribed by the treating physician.

Hyperglycemia in diabetic patients shall be managed by adjusting the insulin dose or other oral medications according to the insulin scheme prescribed by the treating physician.

Storage Conditions:
Do not store above 30°C.

Shelf Life:
3 years from manufacturing date in the proposed storage condition. Do not use after expiry.

Dosage Forms and Packaging Available:
2000mL X 4 PVC Medical plastic collapsible bags per Carton
5000mL x 1 PVC Medical plastic collapsible bag per Carton

Manufacturer / Product Registration Holder:

AIN MEDICARE SDN.BHD.
Lot 4933, 4934 & PT2464, Jalan 6/44, Kaw. Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, MALAYSIA.

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