PRESCRIBING INFORMATION

CANEAL™
Peritoneal Dialysis Solution
(Dextrose 1.5% - Calcium 3.5 mEq/L)

CANEAL™
Peritoneal Dialysis Solution
(Dextrose 2.5% - Calcium 3.5 mEq/L)

and
CANEAL™
Peritoneal Dialysis Solution
(Dextrose 4.25% - Calcium 3.5 mEq/L)

Peritoneal Dialysis Solution

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Chief Medical Supplies Ltd.

CANEAL™ Peritoneal Dialysis Solution (Dextrose 1.5% - Calcium 3.5 mEq/L), CANEAL™ Peritoneal Dialysis Solution (Dextrose 2.5% - Calcium 3.5 mEq/L), and CANEAL™ Peritoneal Dialysis Solution (Dextrose 4.25% - Calcium 3.5 mEq/L)

For Intermittent Peritoneal Dialysis (IPD), Continuous Ambulatory Peritoneal Dialysis (CAPD), or Automated Peritoneal Dialysis (APD)

For Intraperitoneal Administration Only

SUMMARY PRODUCT INFORMATION:

Route of Administration	**Dosage Form / Strength**	**All Nonmedicinal Ingredients**
intraperitoneal	Peritoneal Dialysis Solution-(Dextrose 1.5%-Calcium 3.5 mEq/L), (Dextrose 2.5%-Calcium 3.5 mEq/L), & (Dextrose 4.25%-Calcium 3.5 mEq/L)	NaOH (pH adjustment) HCl (pH adjustment) Water for Injection

DESCRIPTION

CANEAL™ Peritoneal Dialysis Solution is a sterile, nonpyrogenic solution for intraperitoneal administration only. CANEAL™ Peritoneal Dialysis Solution contains no bacteriostatic or antimicrobial agents or added buffers.

Composition, approximate osmolarity, approximate pH, and approximate ionic concentrations are shown in Table 1.

The osmolarities shown in Table 1 are calculated values. As an example, measured osmolarity by freezing point depression determination of CANEAL™ with 1.5% dextrose is approximately 347 mOsmol/L, compared with measured values in normal human serum of 275 - 290 mOsmol/L.

The plastic container is fabricated from a specially formulated polyvinyl chloride (PL146 Plastic). Water can permeate from inside the container into the overpouch in amounts insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

INDICATIONS AND USAGE

CANEAL™ Peritoneal Dialysis Solution is indicated for patients in acute or chronic renal failure when nondialytic medical therapy is judged to be inadequate (Vaamonde and Perez 1977). It may also be indicated in the treatment of certain fluid and electrolyte disturbances, and for patients intoxicated with certain poisons and drugs (Knepshield et al. 1977). However, for many substances other methods of detoxification have been reported to be more effective than peritoneal dialysis (Vaamonde and Perez 1977; Chang 1977).

CONTRAINDICATIONS

CANEAL™ Peritoneal Dialysis Solution is contraindicated in patients with:

- Pre-existing severe lactic acidosis.
- Uncorrectable mechanical defects that prevent effective peritoneal dialysis or increase the risk of infection.
- Documented loss of peritoneal function or extensive adhesions that compromise peritoneal function.

WARNINGS AND PRECAUTIONS

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 Peritoneal Dialysis Solution (Dextrose 1.5% - Calcium 3.5 mEq/L), (Dextrose 2.5% - Calcium 3.5 mEq/L), AND (Dextrose 4.25% - Calcium 3.5 mEq/L). Infrequently, fatal outcomes of EPS have been reported with Peritoneal Dialysis Solution (Dextrose 1.5% - Calcium 3.5 mEq/L), (Dextrose 2.5% - Calcium 3.5 mEq/L), AND (Dextrose 4.25% - Calcium 3.5 mEq/L).

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.

Solutions containing dextrose 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 (See Contraindications). 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 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, calcium and magnesium levels should be monitored carefully in patients treated with cardiac glycosides.

Diabetics require careful monitoring of blood-glucose levels during and following dialysis with dextrose (glucose)-containing solutions. Dosage of insulin or other treatments for hyperglycemia should be adjusted.

The use of 5 liters of dialysis solution is not indicated in a single exchange. CANEAL™ Peritoneal Dialysis Solution is intended for intraperitoneal administration only. Not for intravenous administration.

Do not administer if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage or if seals are not intact.

The drainage fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.

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

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, large polycystic kidneys, or other conditions that compromise the integrity of the abdominal wall, abdominal surface, or intra-abdominal cavity; (Vaamonde and Perez 1977) and 2) other conditions including aortic graft placement (Misra et al. 1998) and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in these situations, the benefits to the patient must be weighed against the possible complications.

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 such as congestive heart failure, volume depletion, or shock.

Excessive use of CANEAL™ Peritoneal Dialysis Solution with higher dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Potassium is omitted from CANEAL™ Peritoneal Dialysis Solution due to 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 evaluated periodically.

Low calcium CANEAL™ Peritoneal Dialysis Solution. (Dex 1.5% - Ca 3.5 mEq/L) should be considered for management of hypercalcemia. Patients receiving this 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.

Overinfusion of CANEAL™ Peritoneal Dialysis Solution volume into the peritoneal cavity may be characterized by abdominal distension/abdominal pain and/or shortness of breath.

Treatment of CANEAL™ Peritoneal Dialysis Solution overinfusion is to drain CANEAL™ Peritoneal Dialysis Solution from the peritoneal cavity.

Use in Children: The safety and efficacy in children have not been established.

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

PREGNANCY AND LACTATION

Pregnancy Category C. Animal reproduction studies have not been conducted with CANEAL™ Peritoneal Dialysis solutions. It is also not known whether CANEAL™ Peritoneal Dialysis Solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore CANEAL™ Peritoneal Dialysis Solutions should not be used during pregnancy and lactation

ADVERSE REACTIONS

The adverse reactions within this section represent those adverse reactions that are thought to have an association with the use of Peritoneal Dialysis Solution (Dextrose 1.5% - Calcium 3.5 mEq/L), (Dextrose 2.5% - Calcium 3.5 mEq/L), AND (Dextrose 4.25% - Calcium 3.5 mEq/L) or in conjunction with performing the peritoneal dialysis procedure.

Adverse Reactions from Clinical Trials

There are no data available on adverse reactions from controlled clinical trials conducted to evaluate the safety of CANEAL™ Peritoneal Dialysis Solution.

Adverse Reactions: General

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Examples of peritoneal dialysis therapy related class effects include: ileus, bleeding.

Post-Marketing Adverse Reactions

The following adverse reactions have been reported in the post-marketing experience. These reactions are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity.

INFECTIONS AND INFESTATIONS: Fungal peritonitis, Peritonitis bacterial, Catheter related infection

METABOLISM AND NUTRITION DISORDERS: Hypovolemia, Hypervolemia, Fluid retention, Hypokalemia, Hyponatremia, Dehydration, Hypochloremia

VASCULAR DISORDERS: Hypotension, Hypertension

RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS: Dyspnea

GASTROINTESTINAL DISORDERS: Sclerosing encapsulating peritonitis, Peritonitis, Peritoneal cloudy effluent, Vomiting, Diarrhea, Nausea, Constipation, Abdominal pain, Abdominal distension, Abdominal discomfort

SKIN AND SUBCUTANEOUS DISORDERS: Stevens-Johnson syndrome, Urticaria, Rash (including pruritic, erythematous and generalized), Pruritus

MUSCULOSKELETAL, CONNECTIVE TISSUE DISORDERS: Myalgia, Muscle spasms, Musculoskeletal pain

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Generalized edema, Pyrexia, Malaise, Infusion site pain, Catheter related complication

DRUG INTERACTIONS

No interaction studies have been conducted with CANEAL™. The blood concentration of the dialyzable drugs may be reduced by peritoneal dialysis.

OVERDOSE

There is a potential for overdose resulting in hypervolemia, hypovolemia, electrolyte disturbances or hyperglycemia. Excessive use of CANEAL™ Peritoneal Dialysis Solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

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 may be managed according to the specific electrolyte disturbance verified by blood testing. The most probable disturbance, hypokalemia, many 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 (see Incompatibilities section).

Hyperglycemia in diabetic patients may be managed by adjusting the insulin dose or adjusting other treatments for hyperglycemia.

For management of a suspected drug overdose, contact your regional Poison Control Centre immediately.

INCOMPATIBILITIES

Consult with physician. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.
Refer to directions for use accompanying drugs to obtain full information on additives.
If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.

Some drug additives may be incompatible with CANEAL™ Peritoneal Dialysis Solution

- Addition of Potassium

Potassium is omitted from CANEAL™ Peritoneal Dialysis Solution because dialysis may be performed to correct hyperkalemia. In situations where 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. 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 Peritoneal Dialysis Solution (Dextrose 1.5% - Calcium 3.5 mEq/L), (Dextrose 2.5% - Calcium 3.5 mEq/L), AND (Dextrose 4.25% - Calcium 3.5 mEq/L) was evaluated in 6 insulin-dependent diabetic patients undergoing CAPD for ESRD. No interference of Peritoneal Dialysis Solution (Dextrose 1.5% - Calcium 3.5 mEq/L), (Dextrose 2.5% - Calcium 3.5 mEq/L), AND (Dextrose 4.25% - Calcium 3.5 mEq/L) 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 CANEAL™ 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 CANEAL™ (Voges et al. 2004).

- Addition of Antibiotics

No formal clinical drug interaction studies have been performed. It has been reported in the literature that, in vitro studies of the following anti-infectives have demonstrated stability with several different peritoneal dialysis formulations: 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 (de Vin et al. 2009; Henderson et al. 1981, Novarro et al. 1986).

DOSAGE AND ADMINISTRATION

CANEAL™ Peritoneal Dialysis Solutions are intended for intraperitoneal administration only. Not for intravenous administration.

CANEAL™ Peritoneal Dialysis Solution should be administered at a rate that is comfortable for the patient. The volume administered is determined by the prescribing physician.

The mode of therapy (Intermittent Peritoneal Dialysis [IPD], Continuous Ambulatory Peritoneal Dialysis [CAPD] or Automated Peritoneal Dialysis [APD]), the frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.

To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for each exchange. Typically the majority of exchanges will utilize 1.5% and 2.5% dextrose containing peritoneal dialysis solutions, with 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal such that therapy can be individualized according to the patient's need for ultrafiltration (Popovich et al. 1978). As the patient's body weight becomes close to the ideal dry weight, lowering the dextrose (glucose) concentration of CANEAL™ is recommended. CANEAL™ 4.25% dextrose-containing solution is a high osmotic pressure fluid and using it for all exchanges may cause dehydration.

It has been reported in the literature that, the fill volume per exchange depends on body size, usually from 2.0 to 2.5 liters per 1.73 m^2 (Ronco et al. 2000; Keshaviah et al. 1994).

For pediatric patients > 2 years old, 800 to 1400 mL/m^2 per cycle up to a maximum of 2000 mL, as tolerated, is recommended. (Potter et al. 1981; Irwin et al. 1981; Ronnholm and Holmberg, 2006)

Peritoneal dialysis solutions may be warmed in the overpouch to 37° C (98.6°F) to enhance patient comfort. However, only dry heat (for example heating pad, warming plate) should be used. Solutions should not be heated in water or in a microwave oven due to the potential for contamination, patient injury or discomfort.

It has been reported in the literature that, the addition of heparin to the dialysis solution may be indicated to aid in prevention of catheter blockage in patients with peritonitis, or when the solution drainage contains fibrinous or proteinaceous material. 500 to 1000 USP units of heparin per liter of solution has been recommended for adults. For children, 50 USP units per 100 mL of dialysis fluid has been recommended (Goel et al. 1998).

Aseptic technique must be employed throughout the peritoneal dialysis procedure.

Do not administer if the solution is discoloured, cloudy, contains particulate matter or shows evidence of leakage, or if seals are not intact.

The drained fluid should be inspected for the presence of fibrin or cloudiness, which may indicate the presence of peritonitis.

Discard any unused remaining solution.

For single use only.

It is recommended that adult patients being placed on peritoneal dialysis or, in the case of pediatric patients, the selected caretaker, (as well as the patient, when suitable), should be appropriately trained in a program which is under the supervision of a physician.

Intermittent Peritoneal Dialysis (IPD)

For dialysis of acute renal failure patients and maintenance dialysis of chronic renal failure patients, the cycle of instillation, dwell and removal of dialysis fluid is repeated sequentially over a period of hours (8 to 36 hours) as many times per week as indicated by the condition of the patient. For chronic renal failure patients who have residual renal function, maintenance dialysis is often accomplished by periodic dialysis (3 to 5 times weekly) for shorter time periods (8 to 14 hours per session) (Mattocks and El-Bassiouni, 1971).

Continuous Ambulatory Peritoneal Dialysis (CAPD) and Automated Peritoneal Dialysis (APD)
For maintenance of chronic renal failure patients

Patients on CAPD typically perform 4 cycles per day (24 hours). In CAPD, the solution remains in the cavity for dwell times of 4 to 6 hours during the day and approximately 8 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled (Ronco et al. 2000; Keshaviah et al. 1994).

Patients on APD typically perform 3-5 cycles at night and up to 2 cycles during the day. After the last outflow during the night, the equipment is then disconnected from the patient and the dialysate remains in the peritoneum until the next cycle. Additional exchanges can be infused by the cycler machine into the peritoneum during the daytime (Blake et al. 1996; Blake et al. 2011).

ACTION AND CLINICAL PHARMACOLOGY

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.
The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, which is present as a bicarbonate precursor, the ion concentration of electrolytes in similar to those in physiological extracellular fluid. Osmosis and diffusion occur across the peritoneal membrane between the plasma of the patient and the dialysis fluid. These processes result in plasma electrolyte concentrations which approach those

found in the dialyzing fluid, and passage of toxic substances and metabolites, present in high concentrations in the blood, across the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time (dwell time), the fluid is drained by gravity from the cavity.

STORAGE AND STABILITY

The CANEAL™ Peritoneal Dialysis Solution is stored **between 15°C to 30°C**, to allow for suitable temperature tolerances during shelf life and transportation of the DP. The product is stable for 2 years.

Avoid excessive heat. Protect from freezing.

SPECIAL HANDLING INSTRUCTIONS

This is a sterile product, handle using aseptic technique.

DIRECTIONS FOR USE

Use aseptic technique.

For complete system preparation, see directions accompanying ancillary equipment. Warming the CANEAL™ Peritoneal Dialysis Solution, if desired, should be done in the overpouch using dry heat only. For patient comfort, the solution container should be at body temperature (37° C, 98.6° F).

The solution should be comfortably warm to the touch. Store **between 15°C to 30°C**.

To Open

Tear overpouch down side at slit and remove solution container. If supplemental medication is desired, follow the directions below before preparing for administration. Check for minute leaks by squeezing container firmly.

To Add Medication

Additives may be incompatible.

If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.

1. Prepare medication site.
2. Using a syringe with a 1 inch long 19 to 25 gauge needle, puncture resealable medication port and inject.
3. Position container with ports up and evacuate the medication port by squeezing and tapping it.
4. Mix solution and medication thoroughly.

DOSAGE FORMS, COMPOSITION AND PACKAGING

CANEAL™ Peritoneal Dialysis solutions are available in nominal size containers with fill volumes and dextrose concentrations as indicated in Table 1.

TABLE 1

	Fill Volume (mL)	Bag Size (mL)	COMPOSITION/100mL					Approx mOsmol	Approx pH	APPROX mEq/L				
			Dex	Sod Chl	Sod Lact	Cal Chl	Mag Chl			Na	Ca	Mg	Cl	Lact
APD – Automated Peritoneal Dialysis														
PD4 w/ 1.5% Dex and 3.5 mEq Cal	2000	2000	1.5 g	567 mg	392 mg	25.7 mg	15.2 mg	347	5.5	132	3.5	1.5	102	35
PD4 w/ 2.5% Dex and 3.5 mEq Cal	2000	2000	2.5 g	567 mg	392 mg	25.7 mg	15.2 mg	398	5.5	132	3.5	1.5	102	35
PD4 w/ 4.25% Dex and 3.5 mEq Cal	2000	2000	4.25 g	567 mg	392 mg	25.7 mg	15.2 mg	486	5.5	132	3.5	1.5	102	35

	Fill Volume (mL)	Bag Size (mL)	COMPOSITION/100mL					Approx mOsmol	Approx pH	APPROX mEq/L				
			Dex	Sod Chl	Sod Lact	Cal Chl	Mag Chl			Na	Ca	Mg	Cl	Lact
PD4 w/ 1.5% Dex and 3.5 mEq Cal	2000	2000	1.5 g	567 mg	392 mg	25.7 mg	15.2 mg	347	5.5	132	3.5	1.5	102	35
PD4 w/ 2.5% Dex and 3.5 mEq Cal	2000	2000	2.5 g	567 mg	392 mg	25.7 mg	15.2 mg	398	5.5	132	3.5	1.5	102	35
PD4 w/ 4.25% Dex and 3.5 mEq Cal	2000	2000	4.25 g	567 mg	392 mg	25.7 mg	15.2 mg	486	5.5	132	3.5	1.5	102	35

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PATIENT MEDICATION INFORMATION

CANEAL™ Peritoneal Dialysis Solution (Dextrose 1.5% and Calcium 3.5mEq/L)
CANEAL™ Peritoneal Dialysis Solution (Dextrose 2.5% and Calcium 3.5mEq/L)
and
CANEAL™ Peritoneal Dialysis Solution (Dextrose 4.25% and Calcium 3.5mEq/L)

Read this carefully before you start using CANEAL™ Peritoneal Dialysis Solution (Dextrose 1.5% and Calcium 3.5mEq/L), CANEAL™ Peritoneal Dialysis Solution (Dextrose 2.5% and Calcium 3.5mEq/L), and CANEAL™ Peritoneal Dialysis Solution (Dextrose 4.25% and Calcium 3.5mEq/L) and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about CANEAL™ Peritoneal Dialysis Solution (Dextrose 1.5% and Calcium 3.5mEq/L), CANEAL™ Peritoneal Dialysis Solution (Dextrose 2.5% and Calcium 3.5mEq/L), and CANEAL™ Peritoneal Dialysis Solution (Dextrose 4.25% and Calcium 3.5mEq/L).

Serious Warnings and Precautions

- have an aortic graft placement.
- have breathing problems.
- have elevated lactate levels or have a condition known to increase the risk of lactic acidosis (severe low blood pressure, sepsis, liver or kidney failure, inborn errors of metabolism, using drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)).
- have diabetes. Blood glucose levels should be monitored and your dosage of insulin or other treatment for hyperglycemia should be adjusted by your doctor.
- have high or low levels of calcium in your blood.
- are pregnant or intend to become pregnant.
- are breastfeeding.

What is the CANEAL™ Peritoneal Dialysis Solution used for?

CANEAL™ Peritoneal Dialysis Solution is a sterile peritoneal dialysis solution used in patients whose kidneys are not working properly. It removes waste products and water from the blood.

CANEAL™ Peritoneal Dialysis Solution can also be used in some cases of drug intoxication and to correct fluid and electrolyte imbalances.

CANEAL™ Peritoneal Dialysis Solution has not been studied for use in children (younger than 18 years old).

How does CANEAL™ Peritoneal Dialysis Solution work?

CANEAL™ Peritoneal Dialysis Solution contains glucose which draws fluid and wastes from your blood stream into your peritoneal cavity (the space inside your abdomen). The fluids and wastes are removed from your body when the CANEAL™ solution is drained.

What are the ingredients in CANEAL™ Peritoneal Dialysis Solution?

Medicinal ingredients: calcium chloride, dextrose, sodium chloride, sodium lactate and magnesium chloride.
Non-medicinal ingredients: water for injection, sodium hydroxide (pH adjustment), hydrochloric acid (pH adjustment)

CANEAL™ Peritoneal Dialysis Solution comes in the following dosage forms:
Sterile Solution only.

Do not use CANEAL™ Peritoneal Dialysis Solution if:

- have a problem involving your abdominal wall or cavity that cannot be corrected by surgery (e.g. hernia, ileus, adhesions, imperfections in the muscle that separate the abdomen from the chest, or tumours)
- have a problem that increases your risk of an abdominal infection (e.g., skin infections, burns, bowel perforations or recent abdominal surgery)
- have severe peritoneal scarring
- have high levels of lactic acid in your blood (lactic acidosis)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CANEAL™ Peritoneal Dialysis Solution. Talk about any health conditions or problems you may have, including if you:

- have an aortic graft placement.
- have breathing problems.
- have elevated lactate levels or have a condition known to increase the risk of lactic acidosis (severe low blood pressure, sepsis, liver or kidney failure, inborn errors of metabolism, using drugs such as metformin and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)).
- have diabetes. Blood glucose levels should be monitored and your dosage of insulin or other treatment for hyperglycemia should be adjusted by your doctor.
- have high or low levels of calcium in your blood.
- are pregnant or intend to become pregnant.
- are breastfeeding.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CANEAL™ Peritoneal Dialysis Solution:

If you are allergic to corn or corn products, undesirable allergic reactions, including development of rash, hives, throat and/or facial swelling, wheezing, shortness of breath, low blood pressure, and other 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 allergic reaction develop and seek immediate medical help.

Patients on CANEAL™ Peritoneal Dialysis Solution may experience high or low levels of potassium, calcium, or magnesium in their blood. Your doctor will monitor your blood test results.

Keep a written note of your weight, a record of the volume liquids added to your body including peritoneal dialysis solutions infused and liquids drunk and the volume of liquids removed from your body including the volume of the peritoneal dialysis solution drained and urine volume, together with any other measurements which your doctor has asked you to record. Contact your doctor, nurse or pharmacist if your drained volume is more than expected.

Protein, amino acids, water soluble vitamins and other medicines may be removed during peritoneal dialysis. **Your doctor may recommend supplementation to your diet and other changes.**

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

Driving and using machines: Before doing tasks which require special attention, wait until you know how you respond to CANEAL™ Peritoneal Dialysis Solution. Do not drive or operate machinery if you experience weakness, blurred vision or dizziness.

Interactions with this Medication

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements or alternative medicines.

The blood concentration of drugs that can be removed from the body using dialysis may be reduced by peritoneal dialysis.

If you are taking heart medicines known as cardiac glycosides (such as digoxin), or insulin your doctor will monitor you closely during treatment.

Proper Use of This Medication

CANEAL™ Peritoneal Dialysis Solution is to be administered into your peritoneal cavity. This is the cavity in your abdomen (belly) between your skin and the peritoneum. The peritoneum is the membrane surrounding your internal organs such as your intestines and liver. This solution is only for intraperitoneal usage, and will be administered via a catheter directly to the peritoneal cavity. It is not for intravenous use.

Always use this medicine exactly as instructed by the medical team specialized in peritoneal dialysis. Check with them if you are not sure.

Usual adult dose:
The kind of treatment (Intermittent Peritoneal Dialysis [IPD], Continuous Ambulatory Peritoneal Dialysis [CAPD] or Automated Peritoneal Dialysis [APD]), frequency of treatment, exchange volume, the time that the dialysis solution remains in the abdominal cavity and length of dialysis will be selected by your doctor. Infuse CANEAL™ Peritoneal Dialysis Solution at a rate that is comfortable for you.

Patients on intermittent peritoneal dialysis (IPD) typically perform 3 to 5 cycles in a week.
Patients on continuous ambulatory peritoneal dialysis (CAPD) typically perform 4 cycles per day (24 hours).
Patients on automated peritoneal dialysis (APD) typically perform 3-5 cycles at night and up to 2 cycles during the day.

The fill volume depends on body size, usually from 2.0 to 2.5 liters per 1.73 m2. To reduce the risk of dehydration, it is important to use the solution(s) your doctor has chosen for you.

Directions for use:

- Detailed instructions and training on the peritoneal dialysis exchange procedure will be given to you, in a specialized training centre, before you use CANEAL™ at home.
- You should practice infection free technique throughout the bag change procedure.
- Examine the bag before use and discard the package if it is broken, damaged, or the solution is discoloured, cloudy or any solids are floating in the solution.
- To make using CANEAL™ Peritoneal Dialysis Solution more comfortable, you can warm it to 37˚C (98.6˚F) before use. This should only be done using dry heat, such as a heating pad or cycler warming plate. To avoid increased risk of infection, do not place CANEAL™ in water to heat the bags. Do not microwave.
- Tear the overpouch down the side at the slit and remove the solution container. The container should be squeezed firmly to check for leaks. **If leaks are found, discard the bag.**

- When draining the fluid after the dwell, always check your drained fluid for cloudiness or fibrin. Fibrin looks like clumps or stringy material in the drained solution. Cloudy drained fluid or fibrin may mean you have an infection. Call your doctor if your drained fluid is cloudy or contains fibrin.

Your doctor may prescribe other injectable drugs to be added directly into the CANEAL™ Peritoneal Dialysis Solution bag. In that situation, add the drug through the medication port. **If the resealable rubber plug on the medication port is missing or partially removed do not use the CANEAL™ bag if medication is to be added.**

- You must use infection free technique when adding any medications to CANEAL™ Peritoneal Dialysis Solution.
- Prepare the medication site.
- Using a syringe with a 1 inch long 19 to 25 gauge needle, puncture the resealable medication port and inject
- Position the container with ports up and evacuate the medication port by squeezing and tapping it.
- Mix the solution and medication thoroughly.
- Use the product immediately after addition of the drug.

CANEAL™ Peritoneal Dialysis Solution is for single use only. Discard any unused remaining solution.

Overdose:

If you think you have taken too much **CANEAL™ Peritoneal Dialysis Solution**, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you have missed an exchange continue with the next scheduled treatment.

What are possible side effects from using CANEAL™ Peritoneal Dialysis Solution?

These are not all the possible side effects you may feel when using **Peritoneal Dialysis Solution.** If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Side effects may include:

- Rash, itching
- Vomiting, nausea, diarrhea, constipation
- Abdominal pain, distention and/or discomfort
- Muscle pain/cramps pain/cramps

If any of these affects you severely, tell your doctor, nurse or pharmacist.

Sometimes too much Peritoneal Dialysis Solution can get into your peritoneal cavity. If you experience abdominal distention, feeling of fullness and or shortness of breath, contact your doctor, nurse, pharmacist or peritoneal dialysis unit.
Encapsulating peritonitis Sclerosis (EPS) is a rare but serious side effect that happens to patients using Peritoneal Dialysis Solution. In EPS the bowels become blocked due to the growth of a thick layer of fibrin within the peritoneum. Symptoms include fever, abdominal discomfort, constipation, nausea, vomiting or lack of appetite, lack or decreased bowel movements or of passing gas. If this happens to you seek immediate medical help.

Serious Side Effects, How Often They Happen, and What to Do About Them

Symptom/effect	Talk with your doctor, nurse or pharmacist		Seek immediate medical help
	Only if severe	In all cases	
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			**X**
Dehydration: dizziness, weakness, fainting, thirst, dry mouth, constipation, muscle cramps	**X**		
Catheter Blockage/ Infection: Redness, pus, swelling or pain around exit			**X**
Peritonitis (infection in the peritoneal cavity): cloudy or bloody drained fluid, abdominal pain, fever, redness, nausea, upset stomach, vomiting, lack of appetite, weight loss, constipation		**X**	
Edema: Swollen ankles or legs, swelling of the eyes or face	**X**		
Steven-Johnson Syndrome: painful red or purple rash, blisters on your skin, mouth, nose, eyes and genitals			**X**
High Blood Pressure: headaches, vision problems, dizziness, shortness of breath	**X**		
Shortness of breath or chest pain		**X**	
Abnormal Bleeding		**X**	
Increased Blood Sugar: frequent urination, thirst, and hunger	**X**		
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		**X**	

This is not a complete list of side effects while taking CANEAL, contact your doctor, nurse or pharmacist.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

REPORTING SIDE EFFECTS:

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store **between 15°C to 30°C**.
Keep out of reach and sight of children.
Store in original package.
Avoid excessive heat. Protect from freezing.
DO NOT USE AFTER EXPIRY DATE

Do not use CANEAL unless the solution is clear and the container undamaged. Any unused portion should be discarded.

If you want more information about CANEAL™ Peritoneal Dialysis Solution:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website.

This leaflet was prepared by Chief Medical Supplies Ltd.

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