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SOFT FLOW SC Normal Calcium (3.5mEq/L) Peritoneal Dialysis Solution with Dextrose 4.25% w/v

Sodium Chloride....5.376 g/L, Calcium Chloride Dihydrate....0.257 g/L, Magnesium Chloride Hexahydrate....0.051 g/L, Dextrose Anhydrous....42.5 g/L, Sodium Lactate....4.484 g/L, Osmolarity....504.8mOsmol/L(CALC)

What is in this leaflet

1. What SOFT FLOW SC is used for
2. How SOFT FLOW SC works
3. Before you use SOFT FLOW SC
4. How to use SOFT FLOW SC
5. While you are using it
6. Side effects
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11. Serial number

What SOFT FLOW SC is used for

SOFT FLOW SC is a solution for peritoneal dialysis. Kidney failure occurs when the kidneys can no longer function adequately and a person's survival depends upon either a kidney transplant or renal replacement therapy, including dialysis. Dialysis is the process of filtering or cleansing the blood of waste products and excess water and removing them from the body. There are two methods of dialysis treatment - hemodialysis and peritoneal dialysis. Both employ specially formulated solutions to perform blood cleansing.

How SOFT FLOW SC works

Peritoneal dialysis uses the body's own peritoneal or abdominal membrane as a filter to cleanse the blood. The peritoneal membrane lines the peritoneal cavity. A sterile tube called a catheter is inserted by a simple surgical procedure through the wall of your abdominal cavity. This provides an opening through which the dialysis solution can be infused into the abdominal cavity. Waste products pass from the blood stream, through the peritoneal membrane and into the dialysis solution. Blood cells and large molecules such as proteins are retained since they are too large to pass through the membrane. The used dialysis solution is periodically drained from the abdominal cavity and replaced with fresh solution, usually 3-4 times a day. Peritoneal dialysis procedures are easy to learn but it is imperative that you adhere to the procedure taught by your health care professional. There are two ways of performing peritoneal dialysis: Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated Peritoneal Dialysis (APD) (i.e., peritoneal dialysis performed by a machine). PD (Peritoneal Dialysis) offers continuous self-care dialysis.

Before you use SOFT FLOW SC

The exchange procedure involves draining the used dialysis solution containing the waste products, and instilling fresh solution into the peritoneal cavity. This must be performed with great care to avoid infection. The exchange procedure should be undertaken where there is privacy and a clean, well-lit environment: home, office or bathroom. The environment should be clean, dust-free, ventilated but free from draughts.

It is important that the catheter exit site on the abdominal wall is kept clean and free from infection. The catheter must be well-secured. To ensure this, you will be required to examine and cleanse your exit site daily. This must be done in the manner in which you were taught during your peritoneal dialysis education.

Your doctor must supervise you the first time you use this product.

When you must not use it

Do NOT use SOFT FLOW SC:

• If you are allergic to active substances or any of the other ingredients of this medicine

• If you have a surgically un - correctable problem affecting your abdominal wall or cavity or un-correctable problem that increases risk of abdominal infections.

• If you have documented loss of peritoneal function due to severe peritoneal scarring.

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Before you start to use it

Check the product label for the correct volume, Glucose concentration and expiry date. The integrity of the pack should be checked by squeezing the bag and examining carefully for signs of leakage. Ensure that the solution is clear.

Take special care:

• If you have serious problems affecting your abdominal wall or cavity. For example, if you have a hernia or a chronic infectious or inflammatory condition affecting your intestines.

• If you have an aortic graft placement.

• If you have severe breathing difficulties.

• If you experience abdominal pain, increased body temperature or notice cloudiness or particles in the drained fluid.

This may be a sign of peritonitis (inflamed peritoneum) or infection. You should contact your medical team urgently. Note the batch number of the peritoneal dialysis solution bags you were using and bring them along with the drained fluid bag to your medical team. They will decide if the treatment should be stopped or any corrective treatment started.

For example, if you have an infection your doctor may perform some tests to find out which antibiotic will be best for you. Until your doctor knows which infection you have, they may give you an antibiotic that is effective against a wide number of different bacteria. This is called a broad-spectrum antibiotic.

• If you have a high level of lactate in your blood, you are at increased risk of lactic acidosis due to the following conditions:
– you have profoundly low blood Pressure
– you have a blood-infection
– You have acute kidney failure
– You have an inherited metabolic disease
- You are taking metformin (a medicine used to treat diabetes)
– You are taking medicines to treat HIV, especially medicines called NRTIs.

If you have diabetes and use this solution, the dose of your drugs which regulate the blood sugar level (e.g. insulin) should be evaluated on a regular basis. Especially when the peritoneal dialysis treatment is started, or changed, the dose of your diabetes drugs may need to be adjusted.

• If you have an allergy to corn (maize) which may result in Hypersensitivity reactions including a serious allergic reaction called anaphylaxis, stop the infusion immediately and drain the solution from the peritoneal cavity.

• If you have a high level of parathyroid hormone in your blood due to your kidney disease. The low level of calcium in SOFT FLOW SC could worsen hyperparathyroidism. Your doctor will monitor levels of parathyroid hormone in your blood.

• You – possibly together with your doctor – should keep a record of your fluid balance and of your body weight. Your doctor will monitor your blood parameters at regular intervals, particularly salts (e.g. hydrogen carbonate, potassium, magnesium, calcium and phosphate), parathyroid hormone and lipids.

• If you have a high level of hydrogen carbonate in your blood.

• Not to use more solution than your doctor has prescribed. Symptoms of over infusion include abdominal distension, feeling of fullness and shortness of breath.

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•Your doctor will check your potassium level regularly. If it falls too low they may give you some potassium chloride to compensate.

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

• Because a disorder called encapsulating peritoneal sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. You – possibly together with your doctor – should be aware of this possible complication. EPS causes:
– inflammation in your abdomen (belly)
– Thickening of intestines that may be associated with abdominal pain, abdominal distension or vomiting. EPS can be fatal.

Children
Your doctor will assess the risk against the benefit of using this product if you are under 18 years old.

Other medicines and SOFT FLOW SC
• Tell your doctor if you are taking, have recently taken or might take any other medicines.

• If you use other medicines, your doctor may need to increase their dose. This is because peritoneal dialysis treatment increases the elimination of certain medicines.

• Take care if you use heart medicines known as cardiac glycosides (eg. digoxin). You may:
– need potassium and calcium supplements
– develop an irregular heartbeat (an arrhythmia)
– your doctor will monitor you closely during treatment, especially your potassium level.

How to use SOFT FLOW SC
The single most important consideration in Peritoneal dialysis is asepsis, i.e., maintaining very clean conditions during all procedures.

While the exchange procedure is a simple technique to learn, it must be done with great care every time. This is because there is always a risk that you may contaminate the solution and therefore cause an infection.

It will probably be necessary to warm CAPD solutions to body temperature before use.
Use of microwave ovens is not recommended because the product may be damaged, resulting in leakage and risk of infection.
In APD, the machine warms the solution to body temperature before it is installed in the peritoneal cavity.

Administration instructions for CAPD therapy
Put on mask. Clean and/or disinfect hands. Using aseptic technique:

1. Uncoil tubing and drain bag, ensuring that the transfer set is closed.
2. Remove the tip protector from the connector of solution container.
3. Immediately attach the solution container to patient connector (transfer set).
4. Clamp solution line and then break frangible near solution bag. Hang solution container and place the drainage container below the level of the abdomen.
5. Open transfer set to drain the solution from abdomen. If drainage cannot be stablished, contact your clinician. When drainage complete, close transfer set.
6. Remove clamp from solution line and flush new solution to flow into the drainage container for 5 seconds to prime the line. Clamp drain line after flush complete.

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7. Open transfer set to fill. When fill complete, close transfer set.
8. Disconnect SOFT FLOW SC Peritoneal Dialysis Solution 4.25% from transfer set and apply the cap on the transfer set.
9. Upon completion of therapy, discard any unused portion.

Administration instructions for APD therapy

Put on mask. Clean and/or disinfect hands. Using aseptic technique:

1. Remove the tip protector from connector of solution container. Do not reuse the solution or container once the tip protector is removed.
2. Immediately attach the solution container to automated peritoneal dialysis set.
3. Continue therapy as instructed in user manual or accompanying tubing sets for automated peritoneal dialysis. Upon completion of therapy, discard any unused portion.

Several important points must be considered before and during use of SOFT FLOW SC:

1. Use the solutions strictly in accordance with the instructions provided to you during your peritoneal dialysis education.
2. You should dialyse only with the volume of solution and at the frequency prescribed by your doctor or your Dialysis Centre.
3. For the route of administration, please see direction of use above.
4. Do not use the solution unless it is clear and the seal is intact.
5. Aseptic technique must be used at all times.
6. The expected effects of dialysis are correction of acid-base balance and electrolyte disturbances, fluid accumulation and removal of toxic waste products from the blood.
7. Failure to perform dialysis as ordered by your doctor will result in rapid acid-base balance disturbances and fluid accumulation (which may result in pulmonary oedema and electrolyte imbalances including raised serum potassium). This could cause a life-threatening situation.
8. Cessation of dialysis must be in consultation with your doctor or the Renal Unit or Dialysis Centre.
9. An accurate fluid balance record must be kept.
10. You must check your weight regularly to avoid accumulating fluid in your body.
11. You will be required to have regular blood tests in order to monitor your condition.
12. You should regularly visit your doctor or the Renal Unit or Dialysis Centre.

How much to use

Your doctor will prescribe the appropriate glucose strength and the number of bags you must use every day.

Use in children and adolescents

If you are below 18 years, your doctor will assess carefully the prescription of this medicine.

When to use

Use as directed by your doctor

How long to use it

Use as directed by your doctor

If you forget to Administer It

Immediately start your peritoneal dialysis treatment or contact your doctor

If you infuse too much

If you infuse too much SOFT FLOW SC you may get:

- abdominal distension
- a feeling of fullness and/or
- a shortness of breath.

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Contact your doctor immediately. They will advise you what to do. If you have any further questions on the use of this product, ask your doctor.

While you are using it

Things you must do

Discuss with your doctor or dialysis nurse the progress you have experienced during the treatment, whether any complication has occurred, especially during the first few days of therapy. Frequent clinical evaluation and laboratory tests may be required.

Things you must not do

Do not stop peritoneal dialysis without the agreement of your doctor. If you stop the treatment, it may have life-threatening consequences.

Side effects

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.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: ..... or visiting the website: npra.moh.gov.my (Consumer > Reporting).

Storage and Disposal of SOFT FLOW SC

Storage

Store below 30°C.
Protect from light and moisture.
Keep out of the reach of children.

Disposal

Any unused product or waste material should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose a product that is no longer required.

These measures will help to protect the environment.

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Product Description

What it looks like

The solution is clear and not more intensely colored than a tinge of yellow.

Ingredients

-Active ingredient
Sodium Chloride: 5.376 g/L,
Calcium Chloride Dihydrate: 0.257g/L,
Magnesium Chloride Hexahydrate: 0.051g/L,
Dextrose Anhydrous: 42.5 g/L
Sodium Lactate: 4.484 g/L

-Inactive ingredient
Water for injection...qs 1Liter

Batch Number:
Manufactured date:
Expiry Date:
MAL number:
MALXXXXXXXXA

Manufacturer and Product Registration Holder
Peritone Health Sdn. Bhd.
(1079413-W)
Lot 12, Industrial Zone Phase 4,
Kulim Hi-tech Park,
Kedah, Malaysia.

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