

DIANEAL PERITONEAL DIALYSIS SOLUTION

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Dianeal Peritoneal Dialysis Solution. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of you using Dianeal Peritoneal Dialysis Solution against the benefit they expect it will have for you.

It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

What Dianeal Peritoneal Dialysis Solution is used for?

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 - haemodialysis and peritoneal dialysis. Both employ specially formulated solutions to perform blood cleansing.

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 Dianeal Peritoneal Dialysis Solution

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.

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.

How to use Dianeal Peritoneal Dialysis Solution

The single most important consideration in PD 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. Specially designed thermostatically-controlled portable warming boxes are available for this purpose. 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.

Several important points must be considered before and during use of Dianeal® Peritoneal Dialysis Solutions:

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 Kidney Doctor or your Dialysis Centre.
3. For the route of administration, please see Description and Use of Peritoneal Dialysis Solutions above.
4. Do not use the solution unless it is clear and the seal is intact.
5. Aseptic technique must be used 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 Kidney 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 Kidney

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 Kidney Doctor or the Renal Unit or Dialysis Centre.

While you are using Dianeal Peritoneal Dialysis Solution

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.

Side effects

Patients using peritoneal dialysis have experienced one or more of the following unwanted effects: abdominal distension, loss of appetite, constipation, scrotal or labial swelling, backache, postural disturbances, pain on inflow and/or outflow, peritonitis (inflammation/infection of the peritoneal cavity), exit site infection, tunnel infection, muscle weakness and cramps. Any undesirable effect should be reported immediately to your Kidney Doctor or the Renal Unit or Dialysis Centre.

In case of Overdose

If you accidentally infuse a larger volume of Dianeal than prescribed

by your Kidney Doctor, you may experience abdominal distension and pain. If you exceed the number of exchanges prescribed, muscle weakness and cramps may occur. You should seek advice from your Kidney Doctor or the Renal Unit or Dialysis Centre.

Product Descriptions

What Dianeal Peritoneal Dialysis Solution looks like?

Dianeal Peritoneal Dialysis Solutions are supplied in either a single Vialflex plastic bag or a Freeline Solo Twin Bag (solution bag with drainage bag attached).

What is in Dianeal Peritoneal Dialysis Solution?

Dianeal Peritoneal Dialysis Solution contains the following ingredients:

Active Ingredients: Calcium Chloride Hexahydrate, Glucose Monohydrate, Magnesium Chloride Hexahydrate, Sodium Chloride, Sodium Lactate

Inactive Ingredients: Water for Injections, Sodium Hydroxide, Hydrochloric Acid

How to store Dianeal Peritoneal Dialysis Solution

Store Dianeal solutions under clean, dry conditions, protected from physical damage and at temperatures not exceeding 30°C. However, individual bags may be warmed in a warming box to 38°C prior to use. Microwave ovens should not be used (see above). The duration of warming an individual bag should not exceed 1 day.

The expiry date is located on the bottom right-hand corner of the label. Solutions should not be used after the expiry date. Dianeal solution should be clear. If it is not,

do not use that bag; isolate it from your stock and return it to your Dialysis Centre. Do not use solutions from damaged cartons.

Where can you get more information?

Further information can be obtained from your Kidney Doctor, or the Renal Unit or Dialysis Centre of the hospital which provided your peritoneal dialysis education.

Name and address of the Sponsor

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