

1.3.2.1 PATIENT INFORMATION LEAFLET – SINGLE BAG

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

DIANEAL 1,5 ADCO peritoneal dialysis solution (with 1,5 % glucose)

DIANEAL LS 2 ADCO low sodium peritoneal dialysis solution (with 2 % glucose)

DIANEAL LS 4,25 ADCO low sodium peritoneal dialysis solution (with 4,25 % glucose)

DIANEAL 4,25 ADCO peritoneal dialysis solution (with 4,25 % glucose)

Glucose (monohydrate), sodium chloride, sodium lactate, calcium
chloride (dihydrate), magnesium chloride (hexahydrate)

Read all of this leaflet carefully before you start using DIANEAL

ADCO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DIANEAL ADCO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DIANEAL ADCO is and what it is used for
2. What you need to know before you use DIANEAL ADCO

3. How to use DIANEAL ADCO
4. Possible side effects
5. How to store DIANEAL ADCO
6. Contents of the pack and other information

1. What DIANEAL ADCO is and what it is used for

DIANEAL ADCO is a solution for peritoneal dialysis.

It removes water and waste products from the blood. It also corrects abnormal levels of different blood components.

DIANEAL ADCO may be prescribed for you if you have either temporary or permanent kidney failure, severe water retention, electrolyte disturbances or if certain toxins need to be removed from your body.

2. What you need to know before you use DIANEAL ADCO

Do not use DIANEAL ADCO:

- If you are hypersensitive (allergic) to any of the active substances or any of the other ingredients of DIANEAL ADCO (listed in section 6)
- If you have severe lactic acidosis (too much acid in the blood)

Warnings and precautions

Take special care with DIANEAL ADCO:

- If you have serious problems affecting your abdominal (stomach) wall or cavity. For example, if you have a hernia or burns, obesity, or a chronic infectious or inflammatory condition affecting your intestines

- A disorder called encapsulating peritoneal sclerosis (EPS) is a complication of peritoneal dialysis therapy. You should be aware of this possible complication. Symptoms of EPS are: inflammation in your abdomen (stomach), thickening of intestines that may be associated with abdominal pain, abdominal distension or vomiting
- If you have a high risk of severe lactic acidosis (too much acid in the blood). You are at increased risk of lactic acidosis if:
 - you have profoundly low blood pressure or blood-infection that can be associated with acute kidney failure
 - you have a liver or metabolic disease
 - you are taking medicines to treat HIV, especially medicines called nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)
- 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 including bicarbonate, CO₂, potassium, magnesium, calcium and phosphate
- Do not use more solution than your doctor has prescribed. Symptoms of over-infusion include abdominal distension, a feeling of fullness and shortness of breath. If you use too much DIANEAL ADCO during a peritoneal dialysis treatment, it can result in significant removal of water and dehydration
- Your doctor will monitor your blood pressure. Any sudden or progressive drop in blood pressure may be indicative of dehydration
- It is important to use aseptic technique throughout the procedure in order to reduce the possibility of infection. If you experience abdominal pain, increased body temperature or notice cloudiness or particles in the drained fluid, it may be a sign of peritonitis. Your doctor will prescribe you antibiotics together with the dosage for use.

Other medicines and DIANEAL ADCO

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Do not use if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent DIANEAL ADCO may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgement and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which DIANEAL ADCO affects you.

3. How to use DIANEAL ADCO

Do not share medicines prescribed for you with any other person.

The mode of therapy, frequency of treatment, exchange volume, duration of dwell and length of dialysis will be selected by your physician.

DIANEAL ADCO solutions are intended for intraperitoneal administration only. It is not for intravenous (into the vein) administration.

DIANEAL ADCO 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.

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

DIANEAL ADCO solutions are available in single-bag and twin-bag configurations.

Follow the steps below for directions for use for the single-bag configuration. For twin-bag configuration, please refer to the twin-bag patient information leaflet.

Before use

- Inspect the bag(s) visually for particulate matter and discolouration prior to administration. If the bag(s) is damaged, you must discard it.
- Warm the bag(s) in the overpouch to 37 °C using dry heat only. **Never immerse in water or use a microwave to warm the bag.** Do not overheat.

Opening of bags and product inspection:

1. Wash hands thoroughly.
2. Check bag for the following:
 - The solution matches the prescribed type
 - The glucose concentration is as prescribed

- The amount of solution in the bag is correct
 - The expiry date has not passed.
3. Ensure there are no leaks by:
- Wiping condensation from the bag and ensuring bag port is separate from bag panel
 - Squeezing the bag
 - Inspecting all seal areas, port areas and front/back panels for leaks.
4. Tear the container overpouch firmly down the side from top slit and remove. Some opacity of the plastic due to moisture absorption during the sterilisation process may be observed. This is normal and does not affect the solution quality or safety. The opacity should diminish gradually.
5. Remove the overpouch and check the following:
- The solution is clear
 - Pull ring/blue tip protector and medication port are in place.

Addition of supplemental medicine if prescribed:

1. Inspect container to ensure re-sealable rubber medication port is in place. Discard if rubber injection port is not attached to container port.
2. Prepare medication port using aseptic technique.
3. Using a syringe with a 19 to 25 gauge needle, puncture re-sealable medication port and inject medicine.
4. Position container with medication port facing upward. Squeeze and tap medication port to empty solution. Mix solution by vigorously agitating container.

Administration procedure for the single-bag container exchange:

1. Wash hands thoroughly
2. Place bag on table or suspend from support (depending on technique)
3. Remove pull ring/blue tip protector from outlet port of container. If a continuous fluid flow is noted, discard container.
4. Attach to an appropriate automated peritoneal dialysis set. Refer to complete directions in manual and/or directions accompanying automated peritoneal dialysis set.
5. If applicable, break connector frangible by grasping the tubing above the top of the frangible and pulling forward and backward until the frangible separates from base
6. Discard unused portion.

Your doctor will tell you how long your treatment with DIANEAL ADCO will last.

If you have the impression that the effect of DIANEAL ADCO is too strong or too weak, tell your doctor or pharmacist.

If you use more DIANEAL ADCO than you should

If you infuse too much DIANEAL ADCO solution you may get:

- Abdominal distension
- A feeling of fullness and/or
- Shortness of breath.

Contact your doctor immediately. He/she will advise you what to do.

4. Possible side effects

DIANEAL ADCO can have side effects.

Not all side effects reported for DIANEAL ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIANEAL ADCO, please consult your healthcare provider for advice.

If any of the following happens, stop using DIANEAL ADCO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Abdominal pain, abdominal distension or vomiting as they may be symptoms of Encapsulating Peritoneal Sclerosis (EPS) (inflammatory condition leading to bowel obstruction)
- Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)

These are all very serious side effects. If you have them, you may have had a serious reaction to DIANEAL ADCO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Peritonitis (inflamed and infected peritoneum) which can result in fever, weakness, cloudy drained fluid, stomach pain
- Hypokalaemia (decrease of potassium) which can cause muscle weakness, twitching or abnormal heart rhythm
- Fluid retention and swelling
- Hyponatraemia (decrease in sodium) which can cause fatigue, coma, confusion or nausea

- Dehydration
- Hypertension (blood pressure that is higher than usual)
- Hypotension (low blood pressure)
- Dyspnoea (shortness of breath)
- Vomiting
- Diarrhoea
- Nausea
- Constipation
- Abdominal (stomach) pain, discomfort or swelling
- Rash and itching
- Musculoskeletal pain (pain in your muscles or bones)
- Infusion site pain

These are all serious side effects. You may need urgent medical attention.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DIANEAL ADCO.

DIANEAL 1,5 ADCO
DIANEAL LS 4,25 ADCO

Adcock Ingram Critical Care (Pty) Ltd.
Email: Aicc.RegulatoryAffairs@adcock.com

Peritoneal dialysis solution

09 May 2025

For reporting of side effects directly to the Holder of the Certificate of Registration, contact

+27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store DIANEAL ADCO

Store all medicines out of reach of children.

Store at or below 25 °C.

6. Contents of the pack and other information

What DIANEAL ADCO contains

Composition per 1 000 ml

DIANEAL 1,5 ADCO:

Glucose (monohydrate)	15,0 g
Sodium chloride	5,6 g
Sodium lactate	5,0 g
Calcium chloride (dihydrate)	260 mg
Magnesium chloride (hexahydrate)	150 mg
Approximate osmolarity	364 mOsmol/L
Approximate pH	5,5

Approximate ionic concentration (mmol/L):

Sodium	141
Calcium	1,77
Magnesium	0,74

DIANEAL 1,5 ADCO
DIANEAL LS 4,25 ADCO

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Peritoneal dialysis solution

09 May 2025

Chloride	101
Lactate	45

DIANEAL LS 2 ADCO:

Glucose (monohydrate)	20,0 g
Sodium chloride	5,2 g
Sodium lactate	4,6 g
Calcium chloride (dihydrate)	260 mg
Magnesium chloride (hexahydrate)	150 mg
Approximate osmolarity	368 mOsmol/L
Approximate pH	5,5

Approximate ionic concentration (mmol/L):

Sodium	130
Calcium	1,77
Magnesium	0,74
Chloride	94
Lactate	41

DIANEAL LS 4,25 ADCO:

Glucose (monohydrate)	42,5 g
Sodium chloride	5,67 g
Sodium lactate	3,92 g
Calcium chloride (dihydrate)	257 mg

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Peritoneal dialysis solution

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Magnesium chloride (hexahydrate)	152 mg
Approximate osmolarity	486 mOsmol/L
Approximate pH	5,5

Approximate ionic concentration (mmol/L):

Sodium	132
Calcium	1,75
Magnesium	0,75
Chloride	102
Lactate	35

DIANEAL 4,25 ADCO:

Glucose (monohydrate)	42,5 g
Sodium chloride	5,6 g
Sodium lactate	5,0 g
Calcium chloride (dihydrate)	260 mg
Magnesium chloride (hexahydrate)	150 mg
Approximate osmolarity	503 mOsmol/L
Approximate pH	5,0

Approximate ionic concentration (mmol/L):

Sodium	141
Calcium	1,77

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DIANEAL LS 4,25 ADCO

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Peritoneal dialysis solution

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Magnesium	0,74
Chloride	101
Lactate	45

The active substances are glucose (monohydrate), sodium chloride, sodium lactate, calcium chloride (dihydrate), magnesium chloride (hexahydrate)

The other ingredients are hydrochloric acid and water for injections.

What DIANEAL ADCO looks like and contents of the pack

A clear, colourless or light yellow to amber aqueous solution.

DIANEAL ADCO peritoneal dialysis solutions in VIAFLEX plastic containers in the single-bag configuration are available in the following container sizes with fill volumes and glucose concentrations as indicated below.

Single-bag	Fill volume (mL)	Container size (mL)
DIANEAL 1,5 ADCO (yellow pull ring / blue tip protector)	500	1 000
	1 000	1 000
	1 000	2 000
	2 000	3 000
	2 500	3 000
	5 000	5 000

DIANEAL 1,5 ADCO
DIANEAL LS 4,25 ADCO

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Peritoneal dialysis solution

09 May 2025

DIANEAL LS 2	500	1 000
ADCO	1 000	2 000
(green pull ring /	2 000	3 000
blue tip protector)	2 500	3 000
DIANEAL LS 4,25	1 000	2 000
ADCO	2 000	3 000
(red pull ring / blue	2 500	3 000
tip protector)		
DIANEAL 4,25	1 000	1 000
ADCO	1 000	2 000
(red pull ring / blue	2 000	3 000
tip protector)		

Not all presentation sizes may be marketed.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road

Aeroton

Johannesburg

2013

Tel: +27 11 494 8000

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DIANEAL LS 4,25 ADCO

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Registration number

DIANEAL 1,5 ADCO: L614 (Act 101/1965)

DIANEAL LS 2 ADCO: L615 (Act 101/1965)

DIANEAL LS 4,25 ADCO: X/34/164

DIANEAL 4,25 ADCO: L616 (Act 101/1965)

Namibia:

DIANEAL 1,5 ADCO: NS2 04/34/0297

DIANEAL LS 4,25 ADCO: NS2 04/34/1678

Botswana:

DIANEAL 1,5 ADCO: S2 B9309895

DIANEAL LS 4,25 ADCO: S2 B9306000

Zimbabwe:

DIANEAL 1,5 ADCO: PP 73/23.3.1/181

DIANEAL 4,25 ADCO: PP 73/23.3.1/183