1.3.1.1.1 PROFESSIONAL INFORMATION – SINGLE BAG

SCHEDULING STATUS **S3**

1 NAME OF THE MEDICINE

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)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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
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:

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Glucose (monohydrate)	42,5 g
Sodium chloride	5,67 g
Sodium lactate	3,92 g
Calcium chloride (dihydrate)	257 mg
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
Magnesium	0,74
Chloride	101
Lactate	45

NOTE:

1. **DIANEAL ADCO** peritoneal dialysis solutions are sterile, nonpyrogenic solutions containing no bacteriostatic or antimicrobial agents.
2. The osmolarities are calculated values. As an example, measured osmolarity by freezing point depression determination of **DIANEAL 1,5 ADCO** is approximately 364 mOsmol/L compared with measured values in normal human serum of 280 mOsmol/L.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

DIANEAL 4,25 ADCO and **DIANEAL LS 4,25 ADCO** are only indicated for treatment of renal failure patients with a sodium and water overload, which will manifest by mass gain, oedema and cardiac failure. Even in severely overloaded patients the **DIANEAL 4,25 ADCO** and **DIANEAL LS 4,25 ADCO** should only be used for alternate exchanges and not for successive exchanges.

Indications for use

DIANEAL 1,5 ADCO	Indicated for the patient with low blood pressure who needs dialysis.
DIANEAL LS 2 ADCO	Indicated for the overloaded diabetic patient or for the patient with a slightly raised blood pressure who needs dialysis.
DIANEAL LS 4,25 ADCO	Indicated for the overloaded patient. It should not be used excessively as hyperglycaemia, calorie overload or dehydration may occur.
DIANEAL 4,25 ADCO	Indicated for the overloaded patient. It should not be used excessively as hyperglycaemia, calorie overload or dehydration may occur.

4.2 Posology and method of administration

Posology

The mode of therapy (Intermittent Peritoneal Dialysis (IPD) or Continuous Ambulatory Peritoneal Dialysis (CAPD) or Continuous Cyclic Peritoneal Dialysis (CCPD) (also known as Automated Peritoneal Dialysis (APD)), 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 hypovolaemia and to minimise 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 that exchange.

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, maintenance dialysis often uses periodic dialysis (3 to 5 times weekly) for shorter time periods (8 to 14 hours per session).

Single-bag configuration is used in Continuous Cyclic Peritoneal Dialysis (CCPD) for maintenance dialysis of chronic renal failure patients.

Use as prescribed by a physician.

Method of administration

DIANEAL ADCO is intended for intraperitoneal administration only. Not for intravenous or intra-arterial administration.

DIANEAL ADCO should be inspected visually for particulate matter and discolouration prior to use.

Heating the dialysis solution to 37 °C may decrease discomfort and heat loss and result in increased clearances of urea when compared to solutions at room temperature.
Warming the **DIANEAL ADCO** solution, if desired, should be done in the overpouch using dry heat only. For patient comfort, the solution should be at body temperature (37 °C). The solution container should be comfortably warm to the touch. Exceeding 45 °C solution temperature may be detrimental to the solution; do not overheat. If the warming method itself exceeds 45 °C, frequently check the solution container and remove it from the heat source when the container becomes warm to the touch. Do not immerse in water for warming. **Do not use a microwave to warm the solution.**

Use aseptic technique.

For complete system preparation, see directions accompanying ancillary equipment.

These **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 professional information.

***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 for 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 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.

4.3 Contraindications

1. Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
2. Pre-existing severe lactic acidosis

4.4 Special warnings and precautions for use

Peritoneal dialysis should be done with great care, if at all, in patients with a number of abdominal conditions including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, faecal fistula or colostomy, tense ascites, obesity, and large polycystic kidneys. Other conditions include recent aortic graft replacement and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

Additives may be incompatible (see section 6.2). When introducing additives, use aseptic technique. Mix thoroughly. Do not store.

Electrolyte, fluid and nutritional imbalances

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.

Excessive use of **DIANEAL ADCO** with 4,25 % glucose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

In acute renal failure patients, plasma electrolyte concentrations should be monitored periodically during the procedure.

Patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and haematologic factors, as well as other indicators of patient status.

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

Potassium is omitted from **DIANEAL ADCO** solutions because dialysis may be performed to correct hyperkalaemia. In situaions 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 hypokalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician**. Frequent monitoring of serum electrolytes is indicated.

Lactic acidosis

Monitor 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, hepatic failure, inborn errors of metabolism, treatment with medicines such as nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)) before the start of treatment and during treatment with lactate-based peritoneal dialysis solutions. Patients with severe lactic acidosis should not be treated with lactate-based peritoneal dialysis solutions (see section 4.3).

Peritonitis and Encapsulating Peritoneal Sclerosis (EPS)

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection. 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.

4.5 Interaction with other medicines and other forms of interaction

Interaction studies have not been performed.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

a. Summary of the safety profile

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.

b. Tabulated summary of adverse reactions

System organ class	Preferred term	Frequency
Infections and infestations	Fungal peritonitis Peritonitis bacterial	Unknown

	Catheter related infection	
Metabolism and nutrition disorders	Hypokalaemia Fluid retention Hypervolaemia Hypovolaemia Hyponatraemia Dehydration Hypochloraemia	Unknown
Vascular disorders	Hypertension Hypotension	Unknown
Respiratory, thoracic, and mediastinal disorders	Dyspnoea	Unknown
Gastrointestinal disorders	Sclerosing encapsulating peritonitis Peritonitis Peritoneal cloudy effluent Vomiting Diarrhoea Nausea Constipation Abdominal pain Abdominal distension	Unknown

	Abdominal discomfort	
Skin and subcutaneous disorders	Stevens-Johnson syndrome Urticaria Rash (including pruritic, erythematous and generalised) Pruritus	Unknown
Musculoskeletal and connective tissue disorders	Myalgia Muscle spasms Musculoskeletal pain	Unknown
General disorders and administrative site conditions	Generalised oedema Pyrexia Malaise Infusion site pain	Unknown

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website.

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.

4.9 Overdose

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 34 (Other)

Pharmacotherapeutic group: Blood substitutes and perfusion solutions, peritoneal dialytics

ATC code: BO5DB

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.

It is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated to attempt to normalise plasma electrolyte concentrations resulting from osmosis and diffusion across the peritoneal membrane (between the patient's plasma and the dialysis fluid). Toxic substances and metabolites, present in high concentrations in the blood, cross the peritoneal membrane into the dialysing fluid. Glucose in the dialysing 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (pH adjuster) and water for injections.

6.2 Incompatibilities

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. If, in the informed judgement 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.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

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	500 1 000 1 000	1 000 1 000 2 000

(yellow pull ring / blue tip protector)	2 000 2 500 5 000	3 000 3 000 5 000
DIANEAL LS 2 ADCO (green pull ring / blue tip protector)	500 1 000 2 000 2 500	1 000 2 000 3 000 3 000
DIANEAL LS 4,25 ADCO (red pull ring / blue tip protector)	1 000 2 000 2 500	2 000 3 000 3 000
DIANEAL 4,25 ADCO (red pull ring / blue tip protector)	1 000 1 000 2 000	1 000 2 000 3 000

Not all presentation sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Critical Care (Pty) Ltd

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8 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)

9. DATE OF FIRST OF AUTHORISATION

Approved: 1992

10. DATE OF REVISION OF THE TEXT

Date amended: 09 May 2025

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

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