

1.3.2 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PHYSIONEAL 40 GLUCOSE 1,36 % w/v / 13,6 mg/ml

PHYSIONEAL 40 GLUCOSE 2,27 % w/v / 22,7 mg/ml

PHYSIONEAL 40 GLUCOSE 3,86 % w/v / 38,6 mg/ml

(SOLUTION FOR PERITONEAL DIALYSIS)

Glucose monohydrate equivalent to anhydrous glucose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium bicarbonate and sodium lactate

Contains sugar:

PHYSIONEAL 40 GLUCOSE 1,36 % w/v / 13,6 mg/ml:

Anhydrous glucose: 13,6 g/l

PHYSIONEAL 40 GLUCOSE 2,27 % w/v / 22,7 mg/ml:

Anhydrous glucose: 22,7 g/l

PHYSIONEAL 40 GLUCOSE 3,86 % w/v / 38,6 mg/ml:

Anhydrous glucose: 38,6 g/l

Read all of this leaflet carefully before you start using PHYSIONEAL 40

GLUCOSE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

- PHYSIONEAL 40 GLUCOSE 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 PHYSIONEAL 40 GLUCOSE is and what it is used for
2. What you need to know before you take PHYSIONEAL 40 GLUCOSE
3. How to take PHYSIONEAL 40 GLUCOSE
4. Possible side effects
5. How to store PHYSIONEAL 40 GLUCOSE
6. Contents of the pack and other information

1. What PHYSIONEAL 40 GLUCOSE is and what it is used for

PHYSIONEAL 40 GLUCOSE is used whenever peritoneal dialysis is employed as well as in patients in whom solutions based on lactate buffer only, with a low pH, cause abdominal inflow pain or discomfort.

For patients with renal failure peritoneal dialysis is used to remove toxic substances produced by nitrogen metabolism and which are normally excreted by the kidneys, and for aiding the regulation of fluid and electrolyte as well as acid base balances.

2. What you need to know before you use PHYSIONEAL 40 GLUCOSE

Do not use PHYSIONEAL 40 GLUCOSE:

- If you are hypersensitive (allergic) to PHYSIONEAL 40 GLUCOSE or to any of the ingredients of PHYSIONEAL 40 GLUCOSE listed in section 6;
- If you have a surgically uncorrectable problem affecting your stomach wall or cavity or uncorrectable problem that increases risk of stomach infections;

- If you have documented loss of peritoneal (The membrane that lines the walls of the abdomen and the pelvis) function due to severe peritoneal scarring.

Warnings and precautions

Take special care with PHYSIONEAL 40 GLUCOSE:

- If you have serious problems affecting your abdominal (stomach) 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 are treated with cardiac glycosides (a chemical that has effects on the heart, stomach, intestines, nervous system) your doctor will monitor your serum potassium levels;
- 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 at regular intervals. Particularly salts (e.g. Bicarbonate, potassium, magnesium, calcium and phosphate), parathyroid hormone and lipids;
- Your doctor will check your potassium levels regularly. If it falls too low, they may give you some potassium chloride to compensate.

Use in diabetic patients

- If you have diabetes and use this solution, the dose of your medicines 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 medicines may need to be adjusted.

Secondary hyperparathyroidism

- If you have a high level of parathyroid hormone in your blood due to your kidney disease. The low level of calcium in PHYSIONEAL 40 GLUCOSE could worsen hyperparathyroidism. Your doctor will monitor levels of parathyroid hormone in your blood.

Metabolic alkalosis

- If you have a high level of bicarbonate in your blood. If you are taking antacids or calcium carbonate, your doctor will monitor your bicarbonate levels.

Encapsulating Peritoneal Sclerosis (EPS)

- PHYSIONEAL 40 GLUCOSE can cause encapsulating peritoneal sclerosis (EPS)
- Symptoms of EPS are: inflammation in your abdomen (stomach), thickening of intestines that may be associated with abdominal pain, abdominal distension or vomiting. EPS can be fatal.

Peritonitis

- If peritonitis occurs, your doctor will prescribe you antibiotics together with the dosage for use;
- 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.

Hypersensitivity

- If you have an allergy to maize starch you may experience hypersensitivity reactions to PHYSIONEAL 40 GLUCOSE, including a serious allergic reaction called anaphylaxis. Stop the infusion immediately and drain the solution from the peritoneal cavity.

Use in patients with elevated lactate levels

- You are at increased risk of lactic acidosis if:
 - 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.

Overinfusion

- Do not use more solution than your doctor has prescribed. Symptoms of overinfusion include abdominal distension, a feeling of fullness and shortness of breath. Treatment of PHYSIONEAL 40 GLUCOSE overinfusion is to drain the solution from the peritoneal cavity.

Improper administration

- Improper clamping or priming sequence may result in infusion of air into the peritoneal cavity, which may result in abdominal pain and/or peritonitis;
- If you infuse unmixed solution, then you should immediately drain the solution and use a newly mixed bag.

Other medicines and PHYSIONEAL 40 GLUCOSE

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

(This includes complementary or traditional 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 (e.g. 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.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking this medicine.

Driving and using machines

PHYSIONEAL 40 GLUCOSE may cause dizziness. If you feel dizzy, you should avoid driving and use of machines.

3. How to take PHYSIONEAL 40 GLUCOSE

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

- PHYSIONEAL 40 GLUCOSE 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;
- It is for single use only;
- It is not for intravenous use;

- Use aseptic technique throughout the administration of the solution as you have been trained;
- In case of damage the container should be discarded;
- Always use this medicine exactly as instructed by the medical team specialised in peritoneal dialysis.

How much and how often

Your doctor will prescribe the appropriate glucose strength and the number of bags you must use every day. Your doctor will tell you how long your treatment with PHYSIONEAL 40 GLUCOSE will last.

If you have the impression that the effect of PHYSIONEAL 40 GLUCOSE is too strong or too weak, tell your doctor or pharmacist.

Method of administration

- Use aseptic technique throughout the administration of the solution as you have been trained;
- Warm the bag to body temperature (37 °C). Use only dry heat (for example, heating pad, warming plate). Never immerse in water. Never use a microwave oven to warm the bag;
- After removal of the overpouch, Mix the two chambers thoroughly by breaking the interchamber frangible pin;
- Wait until the upper chamber has completely drained into the lower chamber. Mix gently by pushing with both hands on the lower chamber walls;
- The solution must be infused within 24 hours after mixing;
- Do not use the bag if the solution is cloudy or contains particles, shows evidence of leakage between chambers or to the exterior, or if seals are not intact;
- Ensure all connections are secure before beginning the exchange;

- After use, check that the drained fluid is not cloudy.

If you take more PHYSIONEAL 40 GLUCOSE than you should

In the event of over dose consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

4. Possible side effects

PHYSIONEAL 40 GLUCOSE can have side effects.

Not all side effects reported for PHYSIONEAL 40 GLUCOSE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this PHYSIONEAL 40 GLUCOSE, please consult your healthcare provider for advice.

Undesirable effects of peritoneal dialysis include procedure and solution related problems.

If any of the following happens, stop taking / using PHYSIONEAL 40 GLUCOSE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Abdominal pain
- Bleeding
- Peritonitis (which is followed by abdominal pain, cloudy effluent and sometimes fever)
- Infection around the catheter (signs of inflammation: redness and secretion)
- Catheter blockage
- Shoulder pain
- Hernia of the abdominal cavity (groin lump)

These are all serious side effects. If you have them, you may have had a serious reaction to PHYSIONEAL 40 GLUCOSE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Oedema (fluid retention)
- Asthenia (weakness)
- Fluid retention
- Hypertension (abnormally high blood pressure)
- Weight increased

Less frequent side effects:

- Peritoneal membrane failure
- Dyspepsia (indigestion)
- Flatulence (passing wind)
- Nausea
- Weakness
- Tiredness
- Chills
- Facial oedema (facial swelling)
- Hernia
- Malaise (feeling of discomfort)
- Thirst
- Musculoskeletal pain
- Headache
- Fainting

- Dizziness.
- Respiratory symptoms associated with pulmonary oedema (lung swelling and fluid in the lungs)
- Dyspnoea (shortness of breath)
- Cough
- Electrolyte disturbances (e.g. hypokalaemia, hypocalcaemia)
- Metabolic alkalosis (disturbance of the body's acid/base balance)
- Hypervolaemia (fluid overload)
- Anorexia (lack or loss of appetite for food)
- Dehydration (too much water lost)
- Hyperglycaemia (high blood sugar)
- Lactic acidosis (too much acid in the body)
- Insomnia (sleeplessness)
- Hypotension (low blood pressure)
- Encapsulating peritoneal sclerosis (symptoms of EPS are: inflammation in your abdomen (stomach), thickening of intestines that may be associated with abdominal pain, abdominal distension or vomiting. EPS can be fatal) and cloudy peritoneal effluent (cloudy peritoneum liquid waste)
- Pyrexia (fever)
- Eosinophilia (a higher than normal level of a certain type of white blood cell)
- Angioedema (swelling of the area beneath the skin)
- Rash
- PCO₂ (partial pressure of carbon dioxide) increased

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PHYSIONEAL 40 GLUCOSE.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store PHYSIONEAL 40 GLUCOSE

PHYSIONEAL 40 GLUCOSE has a shelf life of 24 months

Store at or below 25 °C. Do not freeze.

After reconstitution, use within 24 hours.

Discard any unused solution.

KEEP OUT OF REACH OF CHILDREN.

Store in the original package

6. Contents of the pack and other information

What PHYSIONEAL 40 GLUCOSE contains

PHYSIONEAL 40 GLUCOSE 1,36 % w/v / 13,6 mg/ml

Small bag “A”	
Glucose Monohydrate	41,25 g/l
equivalent to Anhydrous Glucose	37,5 g/l
Calcium Chloride Dihydrate	0,507 g/l
Magnesium Chloride Hexahydrate	0,140 g/l

Large bag "B"	
Sodium Chloride	8,43 g/l
Sodium Bicarbonate	3,29 g/l
Sodium Lactate	2,63 g/l
Final solution after mixing	
Glucose monohydrate	15,0 g/l
equivalent to anhydrous glucose	13,6 g/l
Sodium Chloride	5,38 g/l
Calcium Chloride Dihydrate	0,184 g/l
Magnesium Chloride Hexahydrate	0,051 g/l
Sodium Bicarbonate	2,10 g/l
Sodium Lactate	1,68 g/l

1 000 ml of final solution after mixing corresponds to 362,5 ml of solution A and 637,5 ml of solution B. The pH of the final solution is 7,4.

Composition of the final solution after mixing in mmol/l	
Anhydrous Glucose (C ₆ H ₁₂ O ₆)	75,5 mmol/l
Sodium (Na ⁺)	132 mmol/l
Calcium (Ca ⁺⁺)	1,25 mmol/l
Magnesium (Mg ⁺⁺)	0,25 mmol/l
Chloride (Cl ⁻)	95 mmol/l
Bicarbonate (HCO ₃ ⁻)	25 mmol/l
Lactate (C ₃ H ₅ O ₃ ⁻)	15 mmol/l
Osmolarity	344 mOsmol/l

PHYSIONEAL 40 GLUCOSE 2,27 % w/v / 22,7 mg/ml

Small bag "A"	
Glucose Monohydrate	68,85 g/l
equivalent to Anhydrous Glucose	62,6 g/l
Calcium Chloride Dihydrate	0,507 g/l
Magnesium Chloride Hexahydrate	0,140 g/l
Large bag "B"	
Sodium Chloride	8,43 g/l
Sodium Bicarbonate	3,29 g/l
Sodium Lactate	2,63 g/l
Final solution after mixing	
Glucose monohydrate	25,0 g/l
equivalent to Anhydrous Glucose	22,7 g/l
Sodium Chloride	5,38 g/l
Calcium Chloride Dihydrate	0,184 g/l
Magnesium Chloride Hexahydrate	0,051 g/l
Sodium Bicarbonate	2,10 g/l
Sodium Lactate	1,68 g/l

1 litre of final solution after mixing corresponds to 362,5 ml of solution A and 637,5 ml of solution B. The pH of the final solution is 7,4.

Composition of the final solution after mixing in mmol/l	
Anhydrous Glucose	126 mmol/l
Sodium	132 mmol/l
Calcium	1,25 mmol/l
Magnesium	0,25 mmol/l
Chloride	95 mmol/l
Bicarbonate	25 mmol/l
Lactate	15 mmol/l

Osmolarity	395 mOsmol/l
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PHYSIONEAL 40 GLUCOSE 3,86 % w/v / 38,6 mg/ml

Small bag "A"	
Glucose Monohydrate	117,14 g/l
equivalent to Anhydrous Glucose	106,5 g/l
Calcium Chloride Dihydrate	0,507 g/l
Magnesium Chloride Hexahydrate	0,140 g/l
Large bag "B"	
Sodium Chloride	8,43 g/l
Sodium Bicarbonate	3,29 g/l
Sodium Lactate	2,63 g/l
Final solution after mixing	
Glucose monohydrate	42,5 g/l
equivalent to Anhydrous Glucose	38,6 g/l
Sodium Chloride	5,38 g/l
Calcium Chloride Dihydrate	0,184 g/l
Magnesium Chloride Hexahydrate	0,051 g/l
Sodium Bicarbonate	2,10 g/l
Sodium Lactate	1,68 g/l

1 litre of final solution after mixing corresponds to 362,5 ml of solution A and 637,5 ml of solution B. The pH of the final solution is 7,4.

Composition of the final solution after mixing in mmol/l	
Anhydrous Glucose	214 mmol/l
Sodium	132 mmol/l
Calcium	1,25 mmol/l

Magnesium	0,25 mmol/l
Chloride	95 mmol/l
Bicarbonate	25 mmol/l
Lactate	15 mmol/l
Osmolarity	483 mOsmol/l

The active substances are: Glucose monohydrate equivalent to anhydrous glucose, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, sodium bicarbonate and sodium lactate.

The other ingredients are: Water for injections.

What PHYSIONEAL 40 GLUCOSE looks like and contents of the pack

Chamber "A" – A clear, colourless to yellow solution practically free of visible particles.

Chamber "B" – A clear, colourless to yellow solution practically free of visible particles.

- The PHYSIONEAL 40 GLUCOSE solution is hermetically sealed inside a flexible 5 litre two-chambered Viaflex poly (vinyl chloride) container, with the following fill volumes: 1,5 litre, 2 litre and 2,5 litre.
- The upper chamber is fitted with an injection port for medicine admixture to the glucose with electrolytes solution. The lower chamber is fitted with a port for connection to a suitable administration set allowing dialysis operation. The lineo connector contains iodine.
- The bag is sealed inside a transparent over pouch obtained by thermic fusion and made of multilayer copolymers.

- Container volumes after reconstitution: 1 500 ml (544 ml of solution A and 956 ml of solution B), 2 000 ml (725 ml of solution A and 1 275 ml of solution B), 2 500 ml (906 ml of solution A and 1 594 ml of solution B).

Pack types:

The single bag is a two-chamber bag (small bag “A” and large bag “B”) to be used in Automated Peritoneal Dialysis.

The twin bag is a two-chamber bag (small bag “A” and large bag “B”) plus a drain bag with an integrated disconnect system plus an empty drain bag to be used in Continuous Ambulatory Peritoneal Dialysis.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd.

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Johannesburg,

2013

This leaflet was last revised in

Approved: 25 November 2005

Date of current amendment: 17 November 2021

Registration number

PHYSIONEAL 40 GLUCOSE 1,36 % w/v / 13,6 mg/ml: 37/34/0584

PHYSIONEAL 40 GLUCOSE 2,27 % w/v / 22,7 mg/ml: 37/34/0585

PHYSIONEAL 40 GLUCOSE 3,86 % w/v / 38,6 mg/ml: 37/34/0586