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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

DUOSOL 04, Solution for Haemofiltration

(sodium chloride, calcium chloride dihydrate, potassium chloride, magnesium chloride hexahydrate, glucose monohydrate, sodium hydrogen carbonate)

Contains Sugar: Glucose monohydrate (5,49 g) equivalent to glucose anhydrous (5,0 g)

Read all of this leaflet carefully before you are given Duosol 04

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

What is in this leaflet

1. What Duosol 04 is and what it is used for
2. What you need to know before you are given Duosol 04
3. How to use Duosol 04
4. Possible side effects
5. How to store Duosol 04
6. Contents of the pack and other information

1. What Duosol 04 is and what it is used for

Duosol 04 is a solution for haemofiltration. It is intended for use in patients with acute kidney failure, when the kidneys are no longer able to remove waste products from the blood. Continuous haemofiltration is a procedure which is used to remove the waste products from the body which would otherwise be excreted via the kidneys in urine. The solution corrects the fluid balance and ensures that salt (electrolyte) losses are replaced following treatment.

2. What you need to know before you are given Duosol 04

Duosol 04 should not be given if

- you have an abnormally high blood potassium level (hyperkalaemia)
- your blood contains abnormally low acid levels (metabolic alkalosis)

The haemofiltration procedure itself should not be used if

- you have kidney failure in combination with a very high metabolic turnover (hypercatabolic state), in which situation the accumulation of waste products in your body can no longer be corrected by haemofiltration
- you have poor blood flow from the site of insertion of the cannula of the vein
- you have a high risk of bleeding because you receive medicine to prevent blood clotting (systemic anticoagulation).

Warnings and precautions

Tell your doctor or health care provider before you are given Duosol 04.

Before and during haemofiltration your blood pressure, fluid balance, salt (electrolyte) balance, acid-base balance and kidney function will be monitored. Your blood sugar and phosphate levels will regularly be checked.

Furthermore serum potassium concentration will be monitored before and during haemofiltration.

Other medicines and Duosol 04

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

The level of other medicines in your blood may be reduced during haemofiltration and your doctor will take this into account.

Interactions with other medicines can be avoided by ensuring that the correct dose of the solution for haemofiltration is used and by careful monitoring.

The following interactions will be considered:

- Infusions given in intensive care may change the composition of your blood and your fluid status.
- Toxic effects of certain medicines used to treat heart weakness (medicines containing digitalis) may not become apparent if your potassium or magnesium levels are too high or your calcium levels are too low. If those levels are corrected by haemofiltration, the toxic effects may then occur and causeinstance abnormal heart rhytm. If you have low potassium levels or high

calcium levels in your blood, digitalis may have toxic effects at doses lower than those usually used for therapy.

- Vitamin D and medicines containing calcium increase the risk that the calcium level in the blood rises to abnormally high values (hypercalcaemia).
- Additional use of sodium hydrogen carbonate can increase the risk of abnormally low acid levels in the blood (metabolic alkalosis).

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 advise before you are given this medicine.

There are at present no data known regarding the use of solutions for haemofiltration during pregnancy. However, because all the ingredients of this medicine are naturally occurring substances only replacing the same substances lost from the body during haemofiltration, no risks for the child are to be expected during pregnancy and breastfeeding, and no effects on fertility are to be expected.

Driving and using machines

This medicine is normally given to immobile patients in a hospital/dialysis unit. This will exclude driving and using machines.

3. How to use Duosol 04

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

You will not be expected to give yourself Duosol 04. You will only be given this medicine under the direction of a person with experience in haemofiltration techniques.

Your doctor will decide on the proper dose for you, taking into account your clinical status, your body weight and your metabolic condition. Unless otherwise prescribed, a filtration rate of ca.600 – 1200 mL per hour is recommended for patients of all ages for the removal of those substance which are normally excreted in the urine. Nevertheless a maximum filtration rate of 75 L per day should not be exceeded.

You are given the ready-to-use solution for haemofiltration via the tubing of the haemofiltration apparatus (the so-called extracorporeal circulation) using an infusion pump.

If you are given more Duosol 04 than recommended

There have been no reports of life-treatening situations following the administration of the prescribed dose of this medicine. The administration can be stopped immediately, if required.

Unbalanced administration can result in too much or too litlle fluid being present in the body (hyperhydration or dehydration). This situation can become apparent through changes in blood pressure or pulse.

Hydrogen carbonate overdose can occur if a too large volume of solution for haemofiltration is given. This can lead to abnormally low acid levels in the blood (metaboloc alkalosis), less calcium dissolved in the blood (decrease of ionised alcium) or muscle cramps (tetany).

An overdosage can be the cause of a heart failure and/or congested lung and and can cause changes in the salt (electrolyte) balance and acid-base balance.

Since a health care provider will administer Duosol 04, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

Duosol 04 can have side effects.

Not all side effects reported for Duosol 04 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while given Duosol 04, please consult your health care provider for advise.

The following side effects may occur, but the frequency of these side effects is not known (cannot be estimated from available data):

- Too much or too little fluid in the body (hyperhydration or dehydration),
- abnormal salt (electrolyte) levels,
- low blood phosphates levels (hypophosphataemia),

- high blood sugar levels (hyperglycaemia),
- abnormally low acid levels in the blood (metabolic alkalosis),
- high or low blood pressure (hypertension or hypotension),
- feeling sick (nausea),
- being sick (vomiting)
- and muscle cramps.

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 health care provider. 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 Duosol 04.

5. How to store Duosol 04

Store all medicines out of reach of children.

You should not be given this medicine after the expiry date which is stated on the bag and on the carton after "EXP". The expiry date refers to the last day of that month.

Storage conditions:

- Store at or below 25 ˚C.
- Do not refrigerate or freeze.

Storage conditions after preparation of the ready-to-use solution.

- The mixed product should be used immediately.
- The mixed product is physically and chemically stable for 24 hours at 25 ˚C.

6. Contents of the pack and other information

What Duosol 04 contains

	Small Chamber Electrolyte Solution		**Large Chamber Bicarbonate Solution**	
Active Substances:	**555 mL contain**	**per 1000 mL**	**4445 mL contain**	**per 1000 mL**
Sodium chloride	2,34 g	4,21 g	27,47 g	6,18 g
Potassium chloride	1,49 g	2,68 g	-	-
Calcium chloride dihydrate	1,10 g	1,98 g	-	-
Magnesium chloride hexahydrate	0,51 g	0,91 g	-	-
Glucose monohydrate equivalent to glucose anhydrous	5,49 g 5,0 g	9,90 g 9,0 g	-	-

Sodium hydrogen carbonate	-	-	15,96 g	3,59 g
Electrolytes:	**[mmol/ chamber]**	**[mmol/L]**	**[mmol/ chamber]**	**[mmol/L]**
Na^+	40,0	72	660	149
K^+	20,0	36,0	-	-
Ca^{2+}	7,5	13,5	-	-
Mg^{2+}	2,5	4,5	-	-
Cl^-	95,0	171	470	106
HCO_3^-	-	-	190	42,8
Theoretical osmolarity [mOsm/L]	347		297	

Composition of the ready-to-use solution for haemofltration after mixing:

1000 mL ready-to-use solution for haemifiltration contain [mmol/L]:

Na^+	140
K^+	4,0
Ca^{2+}	1,5
Mg^{2+}	0,5
Cl^-	113
HCO_3^-	35,0
Glucose anhydrous	5,6 (equiv. To 1,0 g)

Theoretical osmolarity [mOsm/L]	300
pH	7,0 - 8,0

The other ingredients are:

Electrolyte solution (small chamber)

Hydrochoric acid 25 % (for pH adjustment), water for injections

Bicarbonate solution (large chamber)

Carbon dioxide (for pH adjustment), water for injections

What Duosol 04 looks like and contents of the pack

Solution for haemofiltration

Clear and colourless solution, free from visible particles

This medicine is delivered in a two-chamber bag. Mixing of both solutions by opening the seam between the two chambers results in the ready-to-use solution for haemofiltration.

2 bags of 5000 mL (two-chamber bags, 4445 mL and 555 mL) per carton.

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This leaflet was last revised in

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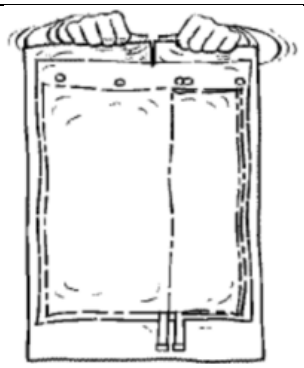
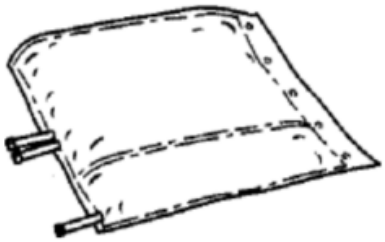
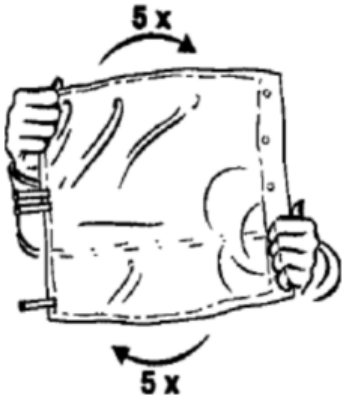
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The following information is intended for healthcare professionals only:

Instructions for preparation of the ready-to-use solution for haemofiltration

The container and the solution must be visually inspected prior to use. The solution for haemofiltration must only be used if the container (outer wrap and two-chamber bag), peel seam and connectors are undamaged and intact and if the solution is clear and colourless and free from visible particles.

Remove outer wrap only immediately before use.

1. Remove the outer wrap	
2. Unfold the bag and place it on a clean, flat surface.	
3. Press with both hands on the smaller chamber of the bag until the peel seam opens fully along its entire length.	
4. Ensure the contents are thoroughly mixed by twisted the bag 5 times back and forth.	

Administration of the ready-to-use solution for haemofiltration

The solution for haemofiltration should be warmed to approximately body temperature by an integrated or external heater. The solution must not be infused under any circumstances if below room temperature.

During application of this medicinal product, white calcium carbonate precipitation has been observed in the tubing lines in rare cases, particularly close to the pump unit and the heating unit. Therefore, the solution in the tubing lines should be closely visually inspected every 30 min during haemofiltration in order to ensure that the solution in the tubing system is clear and free from precipitate. Precipitations may occur also with substantial delay after start of treatment. If precipitate is observed, the solution and the tubing lines must be replaced immediately and the patient carefully monitored.

For single use only. Any unused portion of solution and any damaged containers must be discarded.