

ACCUSOL 35

ACCUSOL 35 Potassium 2 mmol/L

ACCUSOL 35 Potassium 4 mmol/L

Contains the active ingredients calcium chloride dihydrate, glucose monohydrate, magnesium chloride hexahydrate, potassium chloride, sodium chloride, sodium bicarbonate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ACCUSOL 35 haemofiltration solution for injection. It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may want to read it again.

What this medicine is used for

The name of your medicine is ACCUSOL 35 haemofiltration solution for injection. It contains the active ingredients calcium chloride, glucose, magnesium chloride, potassium chloride, sodium chloride and sodium bicarbonate.

ACCUSOL 35 solutions are available in 3 different strengths of potassium, called potassium-free (K0), potassium 2 mmol (K2) and potassium 4 mmol (K4).

It is used in continuous renal replacement therapy (CRRT) to treat patients with serious kidney malfunction. It is administered by injection into the vein, using specialised equipment in intensive care units.

Your doctor or nurse are best positioned to answer any questions you may have about why ACCUSOL 35 has been prescribed for you.

How it works

ACCUSOL 35 solutions purify your blood of waste products; they correct the chemistry and mineral levels in your blood.

As a replacement fluid, it can also be used to provide adequate hydration and mineral levels.

Before you are given this medicine

When you must not be given this medicine

You must not be given this medicine if you have or have had any of the following:

- if you have a high level of potassium in your blood (for ACCUSOL 35 K4)

- if you have a low level of potassium in your blood (for ACCUSOL 35 K0 or K2)
- if you have a high level of bicarbonate in your blood
- if the access to your veins and/or arteries is not good.
- if you have an excessive risk of bleeding

Your doctor or nurse should verify whether any of the above concerns apply to you.

You must not be given this medicine if:

- The expiry date (EXP) printed on the bag has passed.
- The packaging is damaged, leaking or shows signs of prior use or tampering.

Your nurse should verify the above before you are given ACCUSOL 35.

Before you are given it

Before starting the CRRT therapy, your doctor or nurse will ensure there is good access to your veins.

Your doctor or nurse will also ensure that you do not present a high risk of bleeding.

ACCUSOL 35 solutions are available in different potassium and glucose concentrations. Your potassium and glucose blood level will be closely checked to ensure that the most appropriate ACCUSOL 35 solution is used.

Prior to your CRRT therapy with ACCUSOL 35, your doctor should be told if you:

- take any regular medications or other types of medicines from your pharmacy, supermarket or health food shop. This will help with your doctor's choice of ACCUSOL 35 solution and ongoing monitoring of your blood mineral and glucose levels.
- are pregnant or breast-feeding. Your doctor will determine the benefits versus the risks of using ACCUSOL 35 solutions.
- are diabetic, as your blood glucose level will need to be carefully measured. Your insulin dose or blood glucose levels may also need to be adjusted.
- take vitamin D or medicines containing calcium, as your blood calcium levels may be adjusted.
- take medicines for the heart known as cardiac glycosides, your blood potassium levels may need to be modified.

How to take this medicine

ACCUSOL 35 solutions must only be prescribed by a doctor and used in an intensive care unit experienced in CRRT treatment.

ACCUSOL 35 solutions are normally administered by way of the tubing connected to specialised CRRT equipment. Your doctor and nurse are experienced in the treatment technique in their intensive care unit.

ACCUSOL 35 solutions are supplied in specialised medicinal plastic bags with two chambers. Prior to use, your doctor or nurse will thoroughly mix the contents of the two-chambers so that the

ACCUSOL 35 solution is ready to administer.

Your nurse will replace the bag and tubing if any particles are observed in the solution prior to or during use.

How much and how often?

Your doctor will determine the strength of ACCUSOL 35 solution you need for your condition.

Your doctor will also decide on the flow rate and quantity of solution you need to best treat your condition.

For acute kidney injury, CRRT therapy with ACCUSOL 35 solution is carried out for a limited period and stopped when your kidney function has improved.

Overdose

As ACCUSOL 35 solutions are given to you under the direction of an experienced doctor and intensive care team, it is very unlikely that you will receive too much. However, if you think side effects have occurred after receiving ACCUSOL 35 solutions (see 'Side Effects' section below), your doctor or nurse should be told immediately.

While you are taking this medicine

Things you must do

If it appears that your condition or symptoms are getting worse, your doctor or nurse should be told immediately.

During CRRT therapy, your doctor or nurse will carefully check your hydration status (the amount of water in your body), the levels of potassium, other minerals, certain waste products and glucose in your blood.

Your nurse will also check for the very rare possibility of particle formation occurring during CRRT therapy. If any particles are observed in the fluid or tubing during use of ACCUSOL 35, your nurse will replace the bag and tubing.

Side effects

If it appears your condition or symptoms are getting worse while you are receiving ACCUSOL 35 solutions, your doctor or nurse should be told immediately.

All medicines can have side effects. They may not be due to the solutions. As CRRT therapy with ACCUSOL 35 is used to treat serious kidney injury, it is important to monitor whether your condition and symptoms are getting worse.

Your doctor or nurse should be told if you notice any of the following possible side effects to ACCUSOL 35 solutions or to CRRT therapy:

- disturbances in various mineral blood levels (e.g. sodium, potassium, calcium)
- low phosphate blood levels
- changes in blood pressure
- dizziness or light-headedness
- nausea
- vomiting
- bleeding or clotting problems
- infection
- shortness of breath or irregular breathing (on the very rare event that particles have formed in the solution causing air bubbles to get into the blood stream)

Your doctor or nurse should be told if you notice any other unusual symptoms.

Storage

ACCUSOL 35 solutions will be stored in the pharmacy or in the intensive care unit where the temperature stays below 30°C.

Product Description

What it looks like

ACCUSOL 35 are clear and colourless solutions supplied in a specialised plastic bag with two chambers. The two chambers are separated by an inter-chamber seal called the 'long-seal'.

The large chamber 'A' is at the top of the bag and the small chamber 'B' at the bottom is fitted with an access port which is used to connect the bag to suitable administration tubing. Your nurse will first open the long- seal to mix the ACCUSOL 35 solution and prepare it ready use. The shorter "SafetyMoon" seal at the bottom of chamber B will only be opened when your nurse is sure that the ACCUSOL 35 solution is fully mixed and ready for administration.

The two-chamber bag is provided in a protective transparent overpouch.

The volume of ACCUSOL 35 solution after mixing is 5000 mL (3750 mL from chamber A and 1250 mL from chamber B)

ACCUSOL 35 solutions are available as 2x5000 mL bags.

Ingredients

Active ingredients:

- sodium chloride
- sodium bicarbonate
- calcium chloride dihydrate
- magnesium chloride hexahydrate
- glucose (Potassium 2 mmol/L & Potassium 4 mmol/L strengths only)

- potassium chloride (Potassium 2 mmol/L & Potassium 4 mmol/L strengths only)

It also contains the following inactive ingredients:

- dibasic sodium phosphate dihydrate
- water for injections
- hydrochloric acid (for pH adjustment)
- sodium hydroxide (for pH adjustment)

Australian Registration Number

ACCUSOL 35 (K0) replacement fluid solution: AUST R 302424

ACCUSOL 35 Potassium 2 mmol/L (K2) replacement fluid solution: AUST R 302425

ACCUSOL 35 Potassium 4 mmol/L (K4) replacement fluid solution: AUST R 302426

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