MULTIBIC

potassium-free & 4 mmol/l potassium Solutions for Haemofiltration

Contains the active ingredients Calcium chloride, Glucose, Magnesium chloride, Potassium chloride, Sodium chloride, Sodium bicarbonate

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about MULTIBIC potassium-free & 4 mmol/l potassium Solutions for Haemofiltration. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor, nurse or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about being administered this medicine, or
- to obtain the most up-to-date information.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet when your medicine is administered to you. You may want to read it again.

What this medicine is used for

The name of your medicine is MULTIBIC potassium-free &4 mmol/l potassium Solutions for Haemofiltration. It contains the active ingredients Calcium chloride, Glucose, Magnesium chloride, Potassium chloride, Sodium chloride, Sodium bicarbonate.

It is used to treat patients with acute renal failure requiring continuous haemofiltration. It is administered intravenously in ICU units.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

It helps remove toxins from your blood and correct your fluid balance. It also increases the buffer capacity of your blood and thus prevents metabolic acidosis that is your blood becoming too acidic.

Use in children

This medicine should not be used in children unless your doctor has prescribed it.

Before you take this medicine

When you must not take it

Take special care with this medicine

- Do not use MultiBic potassium-free or 4 mmol/L potassium before mixing the two solutions in the double chamber (two-compartment) bag.
- The tubing lines used to apply MultiBic solution should be inspected every 30 minutes. If precipitate is observed within

these tubing lines, bag and tubing lines must be replaced immediately and the patient carefully monitored.

Do not take this medicine if:

You have or have had any of the following:

- You suffer from high (for MULTIBIC 4 mmol/l postassium) or low (for MULTIBIC potassium-free) levels of potassium
- If you have metabolic alkalosis (a condition where there is too much bicarbonate in the blood)
- If haemofiltration is in general the wrong treatment in your situation for the following reasons:
 - excessive protein metabolism (hypercatabolism)
 - an impossibility to achieve a sufficient blood flow through the haemofilter
 - a high risk of bleeding related to medications required to prevent clotting in the haemofilter
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- You have had an allergic reaction to any of the ingredients listed in this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

If your laboratory results show that your serum levels of sodium, calcium, magnesium, phosphate, glucose, acid-base balance, urea and creatinine, body weight and fluid balance are outside of safe levels, you must stop taking this medicine immediately.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

- 1. You have allergies to:
- · any other medicines
- any other substances, such as foods, preservatives or dyes.
- 2. You have or have had any medical conditions, especially the following:
- End Stage Renal Disease
- · Chronic Kidney Disease
- Hypertension
- · Cardiovascular disease
- You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

- You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
- You are planning to have surgery or an anaesthetic.
- 6. You are currently receiving or are planning to receive dental treatment.
- You are taking or are planning to take any other medicines, this includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with this medicine. These include:

- · Electrolyte substitution solutions
- · Parenteral nutrition and other infusions

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with this medicine.

How to take this medicine

Follow carefully all directions given to you by your doctor, nurse or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor, nurse or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Haemofiltration in patients with acute renal failure including the prescription of substitution solutions should be conducted under the direction of a physician with experience in this treatment.

MultiBic solutions containing 0 and 4 mmol/l potassium are exclusively used intravenously.

When to take it

Your doctor will tell you when these solutions are required.

How long to take it for

In acute renal failure treatment is carried out for a limited period and is discontinued when renal function is fully restored.

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

Your doctor will tell you when these solutions are required.

This solution is administered only by healthcare professionals.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- · you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor will check your hydration status (the amount of water in your body), the levels of potassium, other salts, certain waste products, and your blood sugar levels. Your doctor also might advise you about your diet.

The following parameters should be monitored before and during haemofiltration:

Serum potassium, serum sodium, serum calcium, serum magnesium serum phosphate, serum glucose, acid-base status, levels of urea and creatinine, body weight and fluid balance (for the early recognition of hyperand dehydration).

The correct dosing of substitution solutions and strict monitoring of clinical chemistry parameters and vital signs will avoid interactions with other drugs.

Go to your doctor regularly for a check-up. Tell any other doctors, nurses. dentists and pharmacists who are treating you that you take this medicine.

Things you must not do **Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor, nurse or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Your doctor will tell you whether to be careful when driving or operating machinery until you know how this medicine affects you.

Possible side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- nausea (feeling sick)
- muscle cramps

changes in blood pressure

Some side effects might be caused by too much or too little fluid. These are:

- shortness of breath
- · swelling of the ankles and legs
- dehydration (e.g. dizziness, muscle cramps, feeling thirsty)
- blood disorders (e.g. abnormal salt concentrations in your blood)

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

Vomiting

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- Seizures
- Breathlessness
- Swelling of ankles and legs

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, or other parts of the body
- · rash, itching or hives on the skin
- fainting
- · hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor, nurse or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What MULTIBIC potassium-free & 4 mmol/l potassium Solutions for Haemofiltration look like

MULTIBIC potassium-free & 4 mmol/L potassium is provided in a two-compartment bag with 4.75 l of an alkaline hydrogen carbonate solution in one compartment and 0.25 l of an acidic electrolyte, glucose solution in the other compartment.

The clear and colourless solutions are intended for haemofiltration administration.

Ingredients

1000 ml of the mixed solution contain: 6.136 g of Sodium chloride, 0 to 0.2982 g of Potassium chloride, 2.940 g of Sodium hydrogen carbonate, 0.2205 g of Calcium chloride, 0.1017 g of Magnesium chloride; 1.100 g of Glucose as the active ingredients. It also contains the following inactive ingredients:

- Water for injection
- · Hydrochloric acid 25%
- · Carbon dioxide

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

MULTIBIC potassium-free & 4 mmol/l potassium Solutions for Haemofiltration. AUST R 206331, and AUST 206330.

Sponsor

Fresenius Medical Care Pty Ltd 305 Woodpark Road Smithfield NSW 2164 Australia This leaflet was last updated to Rev2 in: July 2019