

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S3**

### POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS

Concentrate for solution for infusion

Potassium chloride

Sugar free

**Read all of this leaflet carefully before you are given POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS**

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

#### **What is in this leaflet**

1. What POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS is and what it is used for
2. What you need to know before you are given POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS
3. How POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS will be administered to you
4. Possible side effects
5. How to store POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS
6. Contents of the pack and other information

## **1 What POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS is and what it is used for**

Potassium naturally occurs in the body fluids. Potassium chloride is used as an electrolyte replacement.

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS is a prescription medicine for the treatment of potassium deficiency in patients for whom dietary measures or oral medicines are inadequate.

## **2 What you need to know before you are given POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS**

**POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS should not be administered to you, if:**

- you are hypersensitive (allergic) to potassium chloride or any of the other ingredients (listed in section 6) of this medicine;
- you have hyperkalaemia (too much potassium in your blood).

### **Warnings and precautions**

***Tell your doctor or healthcare provider before being given the infusion:***

- you have kidney problems (you produce little or no urine);
- if you have heart disease, if you are under treatment with digitalis (medicines used for the treatment of diseases of the heart), and if you have severe or complete heart block;
- if you have low urinary output after surgery (post-operative oliguria) or renal insufficiency (you may form less urine than usual), as the potassium in your blood may become too high (hyperkalaemia) with normal doses of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS;
- if you have conditions which may cause an excess of potassium in the blood (hyperkalaemia): Gamstorp episodic adynamy (muscle hyperexcitability or weakness),

sickle cell anaemia, impaired function of the adrenal glands (adrenal insufficiency), shock with disintegration of red blood cells and/or deficiency of body fluid (shock with haemolytic (rupturing of red blood cells) reactions and/or dehydration (water loss)), metabolic acidosis (form of acidic blood), excess of chloride in the blood (hyperchloraemia);

- if you take potassium-sparing diuretics (medicines used to increase urine excretion that retain potassium in the blood) or use a salt substitute that increases the amount of potassium in your blood (see **Other medicines and POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS**);
- if you have had a recent severe injury damaging a large area of your skin, such as a burn.

*POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS will be given by or under the direct supervision of your doctor, who will take care of the following:*

- Direct injection of potassium chloride concentrates without appropriate dilution may cause instant death.
- The administration should be slow and under control of cardiac activity.
- Since adequate urine flow must be ensured, your urine flow should be monitored.
- Your serum electrolyte levels, and acid-base status should be monitored, and the dose should be adjusted to your individual needs.
- Your doctor should closely monitor you if you have diseases of the heart, acute fluid loss (acute dehydration), heat cramps, and if you are elderly since your kidneys may not work as well or you may have other conditions that may lead to excess of potassium in the blood (hyperkalaemia).
- If signs of renal failure occur, intravenous administration of potassium-containing solutions should be stopped.

Tell your doctor if you notice leakage of infusion fluid into the tissues (extravasation) at the administration site, as it can cause tissue death (necrotic tissue damages).

## **Children**

The safety and efficacy of potassium chloride for paediatric patients has not been fully established.

### **Other medicines and POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

*The following medicines **increases** the amount of potassium in the blood if taken together with POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS:*

- Certain diuretics (“water tablets”) like amiloride, spironolactone and triamterene, (potassium saving medicines). See **If you receive more POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS than you should.**
- Certain medicines for high blood pressure: ACE’s (angiotensin-converting-enzyme) inhibitors (such as captopril) and ARB’s (angiotensin receptor blockers, such as valsartan). If taken together with POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS, these medicines may cause fatal excess of potassium in the blood, particularly if you have renal impairment (weak kidneys).
- Potassium penicillin (an antibiotic).
- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, naproxen, for arthritis and pain.
- Ciclosporin, tacrolimus (used to suppress the immune system following transplants).
- Suxamethonium (used to cause short-term paralysis as part of general anaesthesia during an operation).

*POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS effects the following medicines:*

- Quinidine (used for abnormal heart rhythm): POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS can increase the antidysrhythmic effects of quinidine.
- Thiazides, adrenocorticoids, glucocorticoids, mineralocorticoids. Effects of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS may be decreased.

- Digoxin: too much potassium in the blood (hyperkalaemia) can be dangerous if you take digitalis medicines for the treatment of diseases of the heart.
- Exchange resins (such as colestipol, cholestyramine – used for high cholesterol): the serum levels of potassium are reduced.

### **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 healthcare provider for advice before receiving POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS.

#### ***Pregnancy***

No information available.

#### ***Breastfeeding***

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS is excreted in breast milk. A risk to the newborns/infants cannot be excluded.

#### ***Fertility***

No information available.

### **Driving and using machines**

It is not always possible to predict to what extent POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS affects you.

### **3. How POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS will be administered to you**

You will not be expected to give yourself POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS. It will be given to you by a person who is qualified to do so.

Your doctor will calculate what dose you should receive; this will depend on your serum electrolyte levels, acid-base state and your body weight. The POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS solution will be first diluted and then slowly dripped into a vein. The process may take one or more hours or more, depending on the dose your doctor chose for you.

If you have renal impairment your doctor will prescribe a lower dose.

Your doctor will tell you how long your treatment with POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS will last.

If you have the impression that the effect of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

**If you receive more POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS than you should**

Since a healthcare provider will administer POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

Some of the signs of overdose are irregular heartbeats or heart attack, confusion, muscle paralysis (loss of movement), diarrhoea, difficulties swallowing, tingling sensation in hands and feet, faintness or death.

Please tell your doctor or healthcare provider if you have any concerns.

**If a dose of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS is missed**

Since a healthcare provider will administer POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS, it is unlikely that the dose will be missed.

**4. Possible side effects**

POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS can have side effects.

Not all side effects reported for POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS, please consult your healthcare provider for advice.

**Tell your doctor immediately if notice any of the following side effects:**

- Faintness, irregular or slowed heartbeat, palpitations (feeling your heart), confusion, weak muscles or loss of movement, an odd sensation, typically tingling or pricking ('pins and needles'). These signs may be caused by hyperkalaemia (too much potassium in your blood).
- Pain and redness due to inflammation of the vein or death of tissue at the site of injection.

Your doctor may stop giving you POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS and you will be given urgent medical attention.

**Tell your doctor if you notice any of the following:**

***Frequency unknown:***

- Acidosis (when acid builds up or when bicarbonate (a base) is lost). Some signs are quick heartbeat, confusion, dizziness, headache.
- Hyperchloraemia (an excess of chloride in the blood). Some signs are fatigue, sluggish body, weak muscles, thirst, high blood pressure.
- Venous thrombosis (when a blood clot forms in a vein). Some signs are swelling of the leg, pain or tenderness in the leg, unexplained shortness of breath.
- Nausea (feeling sick).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: [safety.fksa@fresenius-kabi.com](mailto:safety.fksa@fresenius-kabi.com) and to the relevant medicine's regulatory authority in the country where the product is marketed.

## 5. How to store POTASSIUM CHLORIDE 15 % FLEXIVIAL FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C.

The product should be used immediately after opening the ampoule.

Do not use after the expiry date indicated on the label.

Do not dispose of unused medicine in drains or sewerage systems (such as toilets). Return all unused medicine to your pharmacist.

## 6 Contents of the pack and other information

- **The active substance** is potassium chloride.

Each 10 mL of solution contains 1 500 mg (1,5 g) of potassium chloride (15 % *m/v*) equivalent to 20 mmol potassium ions.

- **The other ingredients** are:

Water for injection, hydrochloric acid (for pH adjustment).

Sugar free.

**What POTASSIUM CHLORIDE FRESENIUS 15 % FLEXIVIAL FRESENIUS look like and contents of the pack**

A clear, colourless concentrated solution.

POTASSIUM CHLORIDE FRESENIUS 15 % FLEXIVIAL FRESENIUS is packed in 10 mL polyethylene ampoules (Flexivial) in containers of 20 or 50.

Instructions for the doctor/healthcare provider for handling and correct administration are provided in section 6.6 of the professional information leaflet.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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**Access to the corresponding Professional Information**

The Professional Information is printed and packed with the product.