

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Potassium Chloride 0.15% and Sodium Chloride 0.9% Solution for Infusion

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Potassium Chloride 0.15% and Sodium Chloride 0.9% Solution for Infusion has the following composition:

Name	Specification Reference	% w/v
Sodium Chloride for Injections	EP	0.9
Potassium Chloride	EP	0.15

### **3 PHARMACEUTICAL FORM**

Solution for Infusion

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Potassium replacement therapy.

#### **4.2 Posology and method of administration**

The volume and rate of infusion will depend upon the requirements of the individual patient and the judgement of the physician.

##### Adults

The rate of infusion should not exceed 10-20 mmols of potassium per hour. The total daily dosage of potassium should not exceed 200 mmols of potassium.

##### Children

Correspondingly reduced volumes and rates of infusion may be required.

## Elderly

A reduced volume and rate of infusion may be necessary to avoid circulatory overload, particularly in patients with cardiac or renal insufficiency.

## Method of administration

Solution for Infusion

### **4.3 Contraindications**

Addison's disease, adrenal insufficiency, acute or chronic renal disease, oliguria, anuria and patients with hyperkalaemia.

### **4.4 Special warnings and precautions for use**

Intravenous infusion must be carried out slowly. Caution should be used with administration to patients receiving digitalis therapy, patients with renal or adrenal insufficiency, cardiac disease, acute dehydration or heat cramp, those receiving potassium sparing diuretics and patients with sickle cell haemoglobinopathy.

Caution should be exercised in the volume and rate of infusion since fluid overload and hyperkalaemia may compromise cardiac function. Before administering potassium by the intravenous route, a non-potassium containing hydrating solution should be administered to ensure adequate renal function.

The label states:           Special care in renal failure rapid infusion may be harmful.  
Do not use unless solution is clear and free from particles.  
Contains 10 mmol Potassium (500 ml)  
Contains 20 mmol Potassium (1000 ml)

### **4.5 Interaction with other medicinal products and other forms of interaction**

Care should be exercised in the concurrent administration of potassium containing intravenous solutions and potassium sparing diuretics.

ACE-inhibitors; Cyclosporin; care should be taken when administering to patients with digitalis therapy.

### **4.6 Fertility, pregnancy and lactation**

The safety of this product during pregnancy and lactation has not been established, but its use during these periods is not considered to constitute a hazard.

### **4.7 Effects on ability to drive and use machines**

There is no effect on ability to drive and use machinery.

#### **4.8 Undesirable effects**

Adverse effects are usually due to hyperkalamia and include listlessness, mental confusion, parasthesiae, weakness, hypotension, arrhythmias and sometimes cardiac arrest. Thrombosis of the selected vein may occasionally occur.

##### Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

#### **4.9 Overdose**

Symptoms of overdosage include hypotension, cardiac arrhythmias, heart block and cardiac arrest. Treatment is to stop infusion immediately and if there is persistent acidosis, administer an intravenous infusion of sodium bicarbonate or sodium lactate. Hyperkalaemia may be reversed by the administration of calcium gluconate injection 10% with ECG monitoring.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group:** Blood substitutes and perfusion solutions;  
**Electrolytes**

**ATC code:** B05BB01

Potassium chloride and sodium chloride provide essential ions to maintain the intracellular/extracellular milieu

### **5.2 Pharmacokinetic properties**

Not applicable.

### 5.3 Preclinical safety data

Not Applicable

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Name	Specification Reference	%w/v
Water for Injections in bulk	EP	TO 100
Hydrochloric Acid	EP	QS
Sodium Hydroxide	BP	QS

### 6.2 Incompatibilities

Incompatibilities have been demonstrated in potassium containing solution for infusions with for example, amikacin, amphotericin, benzyl-penicillin and dobutamine.

### 6.3 Shelf life

24 months.

### 6.4 Special precautions for storage

Store at 2° to 25°C

### 6.5 Nature and contents of container

The container is a flexible bag made of medical grade PVC.

- a) A hermetically sealed polythene bag.
- b) A rectangular pouch consisting of polyamide/polythene composite
- c) Polyamide/Polyethylene-Propylene composite laminate welded to polypropylene ethylene propylene composite, plugged with a polycarbonate plug with either a bromobutyl (West 4481/45) or gum (West 7006/45) stopper.

Or

A flexible polyolefine bag sealed in a polyolefine overwrap.

### 6.6 Special precautions for disposal

Opening the overwrap:

Locate the corner tabs at the end of the bag. Grip the two tabs and pull the two halves of the overwrap apart, releasing the bag onto a clean surface.

Setting up the solution:

Position the roller clamp of the giving-set to just below the drip chamber and close. Hold the base of the giving set port firmly and grip the wings of the twist of tab. Twist to remove the protective cover.

Still holding the base of the giving-set port push the set spike fully into the port to ensure a leak proof connection.

Prime the set in accordance with the manufacturer's instructions.

**7      MARKETING AUTHORISATION HOLDER**

Fresenius Kabi Limited  
Cestrian Court  
Eastgate Way  
Manor Park  
Runcorn  
Cheshire  
WA7 1NT

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 08828/0065

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

6<sup>th</sup> June 1989

**10     DATE OF REVISION OF THE TEXT**

27/12/2024