Package leaflet: Information for the user

Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v Solution for Infusion
potassium chloride, sodium chloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v is and what it is used for
2. What you need to know before you are given Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v
3. How Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v is given
4. Possible side effects
5. How to store Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v
6. Contents of the pack and other information

1. What Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v is and what it is used for

Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v is a solution of potassium chloride and sodium chloride in water. Potassium chloride and sodium chloride are chemicals (often called 'salts') that occur naturally in the blood.

This medicine is used to prevent and treat:
- loss of potassiumfrom the body (e.g. after treatment with certain diuretics [water tablets])
- low level of potassium in the blood (hypokalaemia) in situations that may cause potassium chloride and water loss including
  - when you cannot eat or drink, due to illness or after surgery
  - pronounced sweating due to high fever
- sodium chloride- and water-losing conditions

2. What you need to know before you are given Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v

You will not be given Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v:
- if the level of potassium in your blood is higher than normal (hyperkalaemia)
- if the level of chloride in your blood is higher than normal (hyperchloraemia)
- if the level of sodium in your blood is higher than normal (hypernatraemia)
- if you have severe problems with the way your kidneys work (you may produce little or no urine)
- if you have heart failure that is not properly treated (uncompensated cardiac failure) and causes symptoms such as:
  - shortness of breath

- swelling of the ankles
- if you have a condition where the adrenal glands do not function properly (Addison's disease).

Warnings and precautions
This medicine has a higher concentration (hypertonic solution) than the blood. Your doctor will take this into consideration when calculating your dose.

Talk to your doctor or nurse before receiving Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v if you:
- have any type of heart disease or heart failure have reduced kidney function
- have a disease of the adrenal gland that affects the amount of steroid hormones in the body (adrenocortical insufficiency)
- are very dehydrated (loss of water from the body, e.g. from vomiting or diarrhoea)
- have a severe injury involving a large area of skin, such as a burn
- have high blood pressure
- have swelling under the skin, especially around the ankles (peripheral oedema) or in the lungs (pulmonary oedema)
- have high blood pressure during pregnancy (preeclampsia)
- have any other condition when the body retains too much sodium (sodium retention)

You will be closely monitored while being given this medicine. Your doctor will take blood and urine samples to monitor your condition. Special care will be taken if you have heart or kidney problems.

Other medicines and Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v
Tell your doctor if you are taking, have recently taken or might take any other medicines. In particiular, tell your doctor if you are taking:
- cardiac glycosides used in the treatment of heart failure (such as digoxin)
- antiarrhythmic medicines used to suppress abnormal rhythm of the heart (such as quinidine, hydroquinidine, procainamide)
- medicines that increase the concentration of potassium in the blood such as:
    - potassium-sparing diuretics, known as 'water tablets' (such as amiloride, spironolactone, triamterene)
    - ACE inhibitors (mainly used to treat high blood pressure)
    - Angiotensin II receptors antagonists (used to treat high blood pressure)
    - ciclosporin (used to prevent rejection of a transplant)
    - tacrolimus (used to prevent rejection of transplantation and treatment of some skin diseases)
    - medicines that contain potassium
- corticosteroids (anti-inflammatory medicines)

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

This medicine can be used during pregnancy and breast-feeding. The amount of medicine you receive will be carefully monitored by your doctor. Your doctor will also conduct blood tests to monitor the levels of chemicals that are in your blood. This is because changes in the levels of potassium in your blood can affect how your heart and the heart of your unborn baby works.
Your doctor will carefully monitor your blood pressure as sodium chloride can increase it (risk of preeclampsia).

Driving and using machines

This medicine will not affect your ability to drive or operate machinery.

3. How Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v is given

This medicine will be given to you by a doctor or nurse.

Your doctor will decide how much medicine you need and when it will be given. This depends on your age, weight, clinical and biological conditions and how hydrated you are (the amount of water in your body). The amount of medicine you receive may also be affected by other treatments you are receiving.

Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v is given slowly into a vein as an infusion. How quickly you are given the infusion will be determined by your doctor. If you need a large volume or rapid infusion of medicine, your doctor will monitor your ECG (heart activity).

When you are given Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v your doctor will do blood tests to monitor your blood levels of potassium and other electrolytes (such as sodium and chloride) that are normally in the blood. Your doctor will also check that you are urinating normally (adequate urine production).

If you are given more Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v than you should
If you are given too much medicine you may experience: tingling and burning of the arms and legs (paresthesia), muscle weakness, inability to move (paralysis), irregular heartbeat (arrhythmia), heart block (very slow heartbeat), cardiac arrest (the heart stops beating), mental confusion, fluid accumulation in the lungs making breathing difficult (pulmonary oedema), fluid accumulation under the skin especially around the ankles (peripheral oedema), acidification of the blood (acidosis) leading to fatigue, confusion, lethargy and increased respiratory rate.

Tell your doctor immediately if you develop any of these symptoms. Your infusion will be stopped and you will be given treatment depending on your symptoms.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported during post-marketing use of the medicine. The frequency of occurance cannot be estimated from the available data. Side effects may occur due to the technique of administration.

Tell your doctor or nurse if any of the following side effects occur:
- Infection at the injection site
- Abnormal increase in blood volume (hypervolemia)
- Administration of solution into the surrounding tissue (extravasation). This can damage tissue and cause scarring.
- Irritation or pain at the injection site
- Inflammation of the vein in which the solution is infused (phlebitis). This can cause redness, swelling and pain or burning along the vein into which the solution is administered.

- Blood clot at injection site which causes pain, swelling or redness in the area of the clot
- Fever

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via <[To be completed nationally]>. By reporting side effects you can help to provide more information on the safety of this medicine.

5. How to store Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Do not use this medicine if the solution is not clear or has visible particles. Do not use this medicine if the bottle is damaged in any way.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v contains
- The active substances are potassium chloride and sodium chloride. Each ml of solution contains 3 mg potassium chloride and 9 mg sodium chloride.
- Each 500 ml bottle contains 1.50 g potassium chloride and 4.5 g sodium chloride.
- Each 1000 ml bottle contains 3.00 g potassium chloride and 9.00 g sodium chloride.
- The other ingredients are water for injections and sodium hydroxide and hydrochloric acid for pH adjustment.

What Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v looks like and contents of the pack
Potassium Chloride 0.3% w/v and Sodium Chloride 0.9% w/v Solution for Infusion is a clear and colourless solution, free from visible particles. It is available in 500 ml and 1000 ml polyethylene bottles closed with a polyolefin cap containing a polyisoprene rubber stopper. It is supplied in packs of 10 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Belgium	KCl 0.3% w/v & NaCl 0.9% w/v Fresenius Kabi, oplossing voor infusie
Estonia	Potassium Chloride/Sodium Chloride Fresenius
France	Chlorure de potassium 0,3% et chlorure de sodium 0,9% Kabi, solution pour perfusion
Ireland	Potassium Chloride 0.3% w/v & Sodium chloride 0.9% w/v Solution for Infusion
Italy	Sodio Cloruro e Potassio Cloruro Kabi
Latvia	Potassium Chloride/ Sodium Chloride Fresenius 3 mg/9 mg/ml šķīdums infūzijām
Lithuania	Potassium Chloride/ Sodium Chloride Fresenius 3 mg/9 mg/ml infuzinis tirpalas
Poland	Kalii chloridum 0,3% + Natrii chloridum 0,9% Kabi
Portugal	Cloreto de Potássio 0,3% p/v e Cloreto de Sódio 0,9% p/v Kabi
Slovenia	Kalijev klorid/natrijev klorid Kabi 3 mg/9 mg v 1 ml raztopina za infundiranje
Spain	Cloruro de potasio Kabi 0,04 mEq/ml/ en Cloruro de sodio 0,9% solución para perfusion EFG
The Netherlands	KCl 0.3% w/v & NaCl 0.9% w/v Fresenius Kabi, oplossing voor infusie
United Kingdom	Potassium Chloride 0.3% w/v & Sodium chloride 0.9% w/v Solution for Infusion

This leaflet was last revised in <{MM/YYYY}>.

The following information is intended for healthcare professionals only:

Handling & Preparation

This product is for single use only. Any unused solution should be discarded.

Use only if the solution is clear, without visible particles and if the container is undamaged.

Route of administration

The administration is performed by intravenous route using sterile and non - pyrogenic equipment.

Intravenous potassium should be administered in a large peripheral or central vein to diminish the risk of causing sclerosis. If infused through central vein, be sure the catheter is not in the atrium or ventricle to avoid localized hyperkalaemia.

Solutions containing potassium should be administered slowly.

Rate of administration

As administered intravenously, potassium should not be given faster than 15 to 20 mmol/h to avoid a dangerous hyperkalaemia.

In any case, the dosage given under "General Posology" should not be exceeded.

General posology
The recommended dosage for treatment of isotonic fluid depletion (extracellular dehydration) by means of any intravenous solution is:

- for adults: 500 ml to 3 litres/24 h
- for babies and children: 20 to 100 ml per 24 h and per kg of body weight, depending of the age and the total body mass.

Posology

- Adults, Older people and Adolescents:

Typical dose of potassium for the prevention of hypokalaemia may be up to 50 mmol daily and similar doses may be adequate in mild potassium deficiency. When used for treatment of hypokalaemia, the recommended dosage is 20 mmol of potassium over 2 to 3 hours (i. e. 7-10 mmol/h) under ECG control.

- Paediatric population:

When used in the treatment of hypokalaemia the recommended dosage is 0.3-0.5 mmol/kg b.w./h. The dose has to be adjusted on frequently obtained lab values.
The maximal recommended dose of potassium is 2 to 3 mmol/kg b.w./day.

- Patients with renal impairment

Patients with renal impairment should receive lower doses.

Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v is a hypertonic solution, with an approximate osmolarity of 388 mOsm/l.

Administration should be carried out under regular and careful surveillance. Regular monitoring of clinical status, plasma electrolyte concentrations, plasma creatinine levels, BUN level, acid-base balance and ECG is essential in patients receiving potassium therapy, particularly those with cardiac or renal impairment.

Adequate urine flow should be ensured and fluid balance should be monitored.

Potassium salts should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns. In patients under digitalis therapy, regular monitoring of the plasma potassium level is mandatory.

Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, preeclampsia, or other conditions associated with sodium retention

In-use shelf life (Additives)
Chemical and physical stability of any additive medicinal product at the pH of the Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v should be established prior to use.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
It is the responsibility of the doctor to judge the incompatibility of an additive medication towards the solution of Potassium Chloride 0.3 %w/v & Sodium Chloride 0.9 % w/v, by checking a possible change of colour and/or a possible formation of precipitate, insoluble complex or crystals. Refer also to the Summary of Product Characteristics accompanying the additive medicine. Incompatibility of the medicinal product to be added to Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v must be assessed before addition.

The Instructions for Use of the medicinal product to be added must be consulted. Before adding a medicinal product, verify it is soluble and/or stable in water at the pH of Potassium Chloride 0.3% w/v & Sodium Chloride 0.9% w/v (pH: 4.5 to 7.0).
Those additives known to be incompatible should not be used**.**
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.