insoluble complexes or the appearance of crystals. The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify it is soluble and/or stable in water at the pH of Potassium Chloride 0.3% w/v & Glucose 5% w/v (pH: 3.5 to 6.0).

As a guidance the following medications are incompatible with Potassium Chloride 0.3% w/v & Glucose 5% w/v (non-exhaustive listing):
- Amphotericin B
- Dobutamine

Those additives known to be incompatible should not be used.

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place under controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

monitor your ECG (heart activity).

When you are given Potassium Chloride 0.3% w/v & Glucose 5% w/v, your doctor will perform blood tests to monitor your blood levels of:
- potassium
- other electrolytes (such as sodium, and chloride) and other chemical substances that are normally in your blood like creatinine (a breakdown product from the muscles)

If you suffer from poor kidney function, you may receive a lower dose.

If you are given more Potassium Chloride 0.3% w/v & Glucose 5% w/v than you should
If you are given too much of this medicine (over-infusion), 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; a life-threatening situation)
- mental confusion
- acidification of the blood (acidosis) leading to tiredness, confusion, lethargy and increased breathing 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 the 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.

Tell your doctor or nurse if any of the following side effects occur:
- abnormal increase in blood volume (hypervolaemia)
- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn)
- fever
- chills

Side effects that may occur due to the administration technique include:
- infection at the site of infusion
- irritation or pain at the site of infusion (redness or swelling)
- irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is administered.
- formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
- low levels of sodium in the blood (hyponatraemia). Low levels of sodium can lead to brain injury and death due to swelling (cerebral oedema) (see also the section "Warning and precautions").

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
For UK - You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
For Ireland - Via;
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

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

6. Contents of the pack and other information

What Potassium Chloride 0.3% w/v & Glucose 5% w/v contains
- The active substances are potassium chloride and glucose (as monohydrate). Each ml of solution for infusion contains 3.0 mg potassium chloride and 50.0 mg glucose.
- Each 500 ml bottle contains 1.5 g potassium chloride and 25.0 g glucose.
- Each 1000 ml bottle contains 3.0 g potassium chloride and 50.0 g glucose.
- The other ingredients are water for injections and sodium hydroxide and hydrochloric acid for pH adjustment.

What Potassium Chloride 0.3% w/v & Glucose 5% w/v looks like and contents of the pack
Potassium Chloride 0.3% w/v & Glucose 5% w/v Solution for Infusion is a clear solution, free from visible particles. It is available in 500 ml and 1000 ml polyethylene bottles (KabiPac) 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
Marketing Authorisation Holder
MAH for UK:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way,
Manor Park, Runcorn,
WA7 1NT, UK

MAH for IRL:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg
v.d.Höhe, Germany

Manufacturer
Labesfal – Laboratórios Almiro, S.A.
Zona Industrial do Lagedo,
3465-157 Santiago de Besteiros, Portugal

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 & Glucose 5% w/v Fresenius Kabi, oplossing voor infusie
Bulgaria	Калиев хлорид + Глюкоза Каби 3 mg/ml + 50 mg/ml инфузионен разтвор
Estonia	Potassium Chloride/Glucose Fresenius 3 mg/50 mg/ml
France	Chlorure de potassium 0,3% et glucose 5% Kabi, solution pour perfusion
Ireland	Potassium Chloride 0.3% w/v & Glucose 5% w/v Solution for Infusion
Latvia	Potassium Chloride/Glucose Fresenius 3 mg/50 mg/ml šķīdums infūzijām
Lithuania	Potassium Chloride/ Glucose Fresenius 3 mg/50 mg/ml infuzinis tirpalas
Poland	Kalii chloridum 0,3% + Glucose 5% Kabi
Portugal	Cloreto de Potássio 0,3% p/v e Glucose 5% p/v Kabi
Slovenia	Kalijev klorid/Glukoza Kabi 3 mg/50 mg v 1 ml raztopina za infundiranje
Spain	Cloruro de potasio Kabi 0,04 mEq/ml/ en Glucose 5% solución para perfusion EFG
The Netherlands	KCl 0.3% w/v & Glucose 5% w/v Fresenius Kabi, oplossing voor infusie
United Kingdom	Potassium Chloride 0.3% w/v & Glucose 5% w/v Solution for Infusion

This leaflet was last revised in 09/2019.

FRESENIUS KABI

Package leaflet: Information for the user

Potassium Chloride 0.3% w/v & Glucose 5% w/v Solution for Infusion

potassium chloride, glucose monohydrate

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 & Glucose 5% w/v is and what it is used for

Potassium Chloride 0.3% w/v & Glucose 5% w/v is a solution of potassium chloride and glucose in water. Potassium chloride is a chemical substance (often called a 'salt') that occurs naturally in the blood. Glucose is one of the body's sources of energy. This solution provides 200 kilocalories per litre.

This medicine is used as a source of carbohydrates (sugar) in the prevention and treatment of:
- loss of potassium from 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

2. What you need to know before you are given Potassium Chloride 0.3% w/v & Glucose 5% w/v

You will not be given Potassium Chloride 0.3% w/v & Glucose 5% w/v
- if the level of potassium in the blood is higher than normal (hyperkalaemia)
- if the level of chloride in the blood is higher than normal (hyperchloraemia)
- 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)
- if your diabetes is not adequately treated, allowing your blood sugar levels to rise above normal (uncompensated diabetes)
- in states of glucose intolerance, for example:
  - metabolic stress (when the body's metabolism does not function correctly, for example due to severe illness)
  - hyperosmolar coma (unconsciousness). This is a type of coma that can occur if you have diabetes and do not receive enough medicine.
  - a higher amount of sugar in the blood than normal (hyperglycaemia)
  - a higher amount of lactate in the blood than normal (hyperlactataemia)

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 & Glucose 5% w/v if you:
- have any type of heart disease or heart failure
- have respiratory failure (lung disease)
- have reduced kidney function (special monitoring may be required in the above conditions)

- 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, for example from vomiting or diarrhea)
- have a severe injury involving a large area of skin, (such as a burn)
- had a head injury within the past 24 hours
- have a high pressure within the skull (intracranial hypertension)
- have recently had a stroke
- are allergic to corn (Potassium Chloride 0.3% w/v & Glucose 5% w/v contains sugar derived from corn)
- have a condition that could cause high levels of vasopressin, a hormone regulating fluid in your body. You may have too much vasopressin in your body because, for example if:
  - you have had a sudden or serious illness
  - you are in pain
  - you have had surgery
  - you have infections, burns or diseases of the central nervous system
  - you have diseases linked to your heart,liver or kidneys
  - because you are taking certain medicines

This may increase the risk of low levels of sodium in your blood and can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death. Brain swelling increases the risk of death and brain damage. People who are at higher risk of brain swelling are:
- children
- women (particularly if you are of fertile age)
- people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury.

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.

Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein). During long term treatment with Potassium Chloride 0.3% w/v & Glucose 5% w/v you may need to be given extra nutrition.

As Potassium Chloride 0.3% w/v & Glucose 5% w/v infusion contains sugar (glucose), it can cause a high level of sugar in the blood (hyperglycaemia). If this occurs, your doctor may:
- adjust the speed of infusion
- give you insulin to reduce the blood sugar levels

This is particularly important if you are diabetic.

All patients should be closely monitored. In cases where normal regulation of the water content of the blood is disturbed due to increased secretion of Antidiuretic Hormone (ADH), the infusion of fluids with a low concentration of sodium chloride (hypotonic fluids) may result in a low level of sodium in the blood (hyponatraemia). This can lead to headache,nausea,seizures,lethargy,coma, swelling of the brain (cerebral oedema) and death; therefore these symptoms (acute symptomatic hyponatraemic encephalopathy) are considered a medical emergency.

Children
Potassium Chloride 0.3% w/v & Glucose 5% w/v infusion should be given with special care in children.
Newborns, especially born premature and with low birth weight, are at increased risk of developing **a too low or too high level of sugar in the blood** (hypo or hyperglycaemia) due to infusion of glucose solutions.
- **Low level of sugar** in the newborn can cause prolonged seizures, coma and brain damage.
- **High level of sugar** has been associated with bleeding into the brain, late onset bacterial and fungal infection, infection in the intestinal track (necrotizing enterocolitis), affects eyes (retinopathy of prematurity), lungs problems (bronchopulmonary dysplasia), prolonged length of hospital stay, and death.

Children should be closely monitored. In cases where normal regulation of the water content of the blood is disturbed due to increased secretion of Antidiuretic Hormone (ADH), the infusion of fluids with a low concentration of sodium chloride (hypotonic fluids) may result in a low level of sodium in the blood (hyponatraemia). This can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death; therefore these symptoms (acute symptomatic hyponatraemic encephalopathy) are considered a medical emergency.

Other medicines and Potassium Chloride 0.3% w/v & Glucose 5% w/v
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

It is particularly important that you inform 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 receptor antagonists (used to treat high blood pressure)
  - cyclosporin (used to prevent rejection of a transplant)
  - tacrolimus (used to prevent rejection of a transplant and to treat some skin diseases)
  - medicines that contain potassium (such as potassium supplements, salt substitutes containing potassium)
- Some medicines act on the hormone vasopressin. These may include:
  - anti-diabetic medication (chlorpropamide)
  - cholesterol medicine (clofibrate)
  - anti-epileptic medication (carbamazepine)
  - products resembling amphetamine (among others MDMA)
  - some cancer drugs (vincristine, ifosfamide, cyclophosphamide)
  - selective serotonin reuptake inhibitors (used to treat depression)
  - antipsychotics
  - opioids for severe pain relief
  - medicines for pain and/or inflammation (also known as NSAIDs)
  - medicines that imitate or strengthen the effects of vasopressin such as desmopressin (used to treat increased thirst and urination), terlipressin (used to treat bleeding of the gullet) and oxytocin (used to induce labour)
- Other medicinal products increasing the risk of hyponatraemia also include diuretics (water tablets) in general and antiepileptics such as oxcarbazepine.

Potassium Chloride 0.3% w/v & Glucose 5% w/v must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause

them to clump together.

Potassium Chloride 0.3% w/v & Glucose 5% w/v with food and drink
You should ask your doctor about what you can eat or drink.

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 or nurse for advice before taking this medicine.

This medicine can be given 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.

Driving and using machines
This medicine will not affect your ability to drive or use machines.

3. How you will be given Potassium Chloride 0.3% w/v & Glucose 5% w/v

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

Your doctor will decide on how much 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) and the reason for treatment. The amount you are given may also be affected by other treatments you are receiving.

Before and during the infusion, your doctor will monitor the amount of fluid in your body, the acidity of your blood, urine flow and the amount of electrolytes (particularly sodium) in your blood (mainly in patients with high levels of the hormone vasopressin, or who are taking other medicines which increase the effects of vasopressin).

How quickly you are given the infusion will be determined by your doctor.

If you need a large volume or rapid infusion of this medicine, your doctor may

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 via a large peripheral or central vein to diminish the risk of causing sclerosis. If infused through a 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 the treatment of carbohydrates and fluid depletion is

- for adults: 500 ml to 3 litres/24 h

- for babies and children:
  0-10 kg body weight: 100 ml/kg/24h
  10-20 kg body weight: 1000 ml + (50 ml/kg over 10 kg) /24 h
  >20 kg body weight: 1500 ml + (20 ml/kg over 20 kg)/24 h

Posology for prevention and treatment of potassium depletion

V002

- Adults, Older people and Adolescents:

A 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. The maximal recommended dose of potassium is 2 to 3 mmol/kg/24 h.
When used for the 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.

The maximum recommended administration rate should not exceed 15-20 mmol/h.

Patients with renal impairment should receive lower doses.

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

Use in 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 maximum recommended dose of potassium is 2 to 3 mmol /kg b.w./day.

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in paediatric intravenous fluid therapy.

Shelf life after first opening:

Stability of the product after first opening has not been tested, therefore, the product has to be used immediately after first opening.

In-use shelf life (Additives)

Chemical and physical stability of any additive medication at the pH of the Potassium Chloride 0.3% w/v & Glucose 5% 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 physician to judge the incompatibility of an additive medication with the Potassium Chloride 0.3%w/v & Glucose 5% w/v Solution for Infusion by checking for eventual colour change and/or eventual precipitate,