

Package leaflet: Information for the User

B. Braun Medical Limited · Dublin 12, Ireland

Potassium Chloride 15% w/v**Concentrate for Solution for Infusion**

Potassium Chloride

Read all of this leaflet carefully before you receive 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Potassium Chloride 15% w/v is and what it is used for
2. What you need to know before you use Potassium Chloride 15% w/v
3. How to use Potassium Chloride 15% w/v
4. Possible side effects
5. How to store Potassium Chloride 15% w/v
6. Contents of the pack and other information

1. What Potassium Chloride 15% w/v is and what it is used for

Potassium Chloride 15% w/v is a concentrated solution of potassium chloride. It is used to supply potassium to you

- when you are lacking this salt
- when you have a deficit of potassium, especially if it is accompanied by excess alkali and abnormally low chloride levels in your blood (hypochloreaemic alkalosis)
- as part of parenteral nutrition, when you are unable to eat food normally.

2. What you need to know before you use Potassium Chloride 15% w/v**Do not use Potassium Chloride 15% w/v**

- if you have an abnormally high potassium or chloride level in your blood (hyperkalaemia, hyperchloreaemia)

Warnings and precautions

Talk to your doctor before using Potassium Chloride 15% w/v.

Special care with Potassium Chloride 15% w/v is necessary

- if you have heart problems
- if you have a disease where the potassium excretion in the urine is often reduced, such as impaired kidney function, Addison's disease (a specific disease of the adrenal gland), or sickle cell anaemia (an inherited disease of the red blood cells). If your kidney function is severely impaired or if you are on dialysis, your doctor will consult a kidney specialist before giving you this medicine
- if you are taking or receiving medicines that reduce potassium excretion in urine. For example if you are taking:
 - o certain medicines increasing urine flow (diuretics)
 - o certain blood pressure medications (Angiotensin II receptor antagonists, ACE inhibitors)
- if you are taking or receiving medicines that can affect kidney function (e.g. certain medicines suppressing inflammatory processes)
- if you have shock (an acute medical condition accompanied with a fall in your blood pressure, cold skin, rapid heart beat, and irregular breathing which can occur e.g. after you have lost a lot of blood, you have experienced severe burns, you have had an allergic reaction)
- if you suffer from severe tissue damage, such as in burn injuries
- if you suffer from a disorder that causes muscle weakness and sometimes a higher than normal level of potassium in the blood (hyperkalaemic familial periodic paralysis)

Your doctor will take these points into consideration before and during your treatment with this medicine.

If you receive this medicine because you are lacking potassium, you will at first receive no glucose infusion at the same time because glucose may further decrease your potassium levels.

While you are receiving this medicine, your blood electrolyte levels and acid-base balance will be monitored. This will be done to ensure that these are normal. Furthermore, your ECG might be monitored.

It will be made absolutely sure that the solution is administered into your vein in order to avoid tissue damage.

If you receive this medicine because you are lacking potassium, your doctor will usually give it to you using an infusion pump.

Elderly patients, who are more likely to suffer from heart and kidney problems, will be closely monitored during treatment, and the dosage will be carefully adjusted.

If you are very undernourished, i.e. you have not been receiving enough food, there is a chance that you may suffer from a condition called "Refeeding syndrome". Your doctor will monitor you carefully and only increase your nutrient intake slowly.

Other medicines and Potassium Chloride 15% w/v

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, your doctor will have to pay attention to:

- **Medicines for treatment of heart weakness (cardiac glycosides, e.g. digoxin):** The effects of these medicines will become weaker when the blood potassium level rises. They will become stronger (possibly with irregular heartbeat) when your blood potassium level decreases.

Medicines that lower the potassium excretion in urine:

This group of medicines includes

- some medicines increasing the urine flow (potassium-saving diuretics like triamterene, amiloride, spironolactone)
- certain medicines for treatment of high blood pressure (Angiotensin II receptor antagonists or ACE inhibitors)
- medicines that suppress your immune system (tacrolimus, ciclosporin)
- certain medicines used as painkillers or to treat inflammation (non-steroidal anti-inflammatory drugs)
- blood-thinning medicines (heparin)

Giving potassium together with these may lead to very high blood potassium levels. This may affect your heart rhythm.

Medicines that increase the potassium excretion in urine:

The following medicines can increase the potassium excretion in urine:

- a certain hormone (adrenocorticotrophic hormone [ACTH])
- certain medicines to treat inflammation (corticosteroids)
- some medicines increasing the urine flow (loop diuretics)

Giving potassium together with these may lead to you receiving the wrong dose of potassium as the potassium given to you will be lost from your body more quickly than normal.

B | BRAUN**SUMMARY OF PRODUCT CHARACTERISTICS**

B. Braun Medical Limited · Dublin 12, Ireland

1 NAME OF THE MEDICINAL PRODUCT**Potassium Chloride 15% w/v**

Concentrate for Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains

Potassium Chloride 150 mg

1 dosage unit of solution contains

Potassium Chloride 1.50 g

• per 10 ml ampoule [mmol/ml]

Electrolyte concentrations

Potassium 2

Chloride 2

Excipients

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion

Clear solution, free from visible particles.

pH in the range 5.0- 7.0.

4 CLINICAL PARTICULARS**4.1 Therapeutic Indications**

- Treatment of potassium deficiency, in particular if accompanied by hypochloreaemic alkalosis.
- Supplementation of potassium as a part of parenteral nutrition.

4.2 Posology and method of administration**Posology**

The dosage should be adjusted according to the actual serum electrolyte concentrations and the acid base status and the individual requirements of the patient. Potassium concentrates for infusion must be diluted with a compatible i.v. solution prior to administration.

Adults and elderly patients:

Treatment of moderate, asymptomatic potassium deficiency:

The amount required for correction of moderate potassium deficiency and in maintenance may be calculated according to the following formula:

$$\text{mmol K}^+\text{required} = (\text{BW}^*[\text{kg}] \times 0.2)^{**} \times 2 \times (\text{serum-K}^+\text{target}^{***} - \text{serum-K}^+\text{actual} [\text{mmol/l}])$$

*BW = body weight

**Term represents the extracellular fluid volume

***K⁺target should be 4.5 mmol/ per litre

Maximum infusion rate:

Up to 10 mmol potassium per hour (corresponding to 0.15 mmol potassium/kg body weight per hour).

Treatment of severe symptomatic potassium deficiency (serum potassium level below 2.5 mmol/ per litre):

Maximum daily dose:

Up to 2 – 3 mmol/kg body weight/day

Maximum infusion rate:

Up to 20 mmol potassium per hour (corresponding to 0.3 mmol potassium/kg body weight per hour).

If serum potassium levels are below 2 mmol/ per litre and continuous ECG monitoring is ensured, the infusion rate may be as high as 40 mmol per hour.

Potassium supplementation as part of parenteral nutrition:

The daily requirements of potassium are 1– 1.5 mmol/ kg body weight.

The administration rate should not exceed 10 mmol potassium per hour (corresponding to 0.15 mmol potassium/ kg body weight per hour).

Paediatric population

Treatment of potassium deficiency

In children, the solution must be diluted to a concentration of 20–40 mmol of KCl/ per litre before administration.

Maximum daily dose:

The maximum daily dose depends on the severity of potassium deficiency and overall condition of the individual patient. The maximum daily dose might therefore exceed the amount of potassium given as part of parenteral nutrition (see section "Potassium supplementation as part of parenteral nutrition" below).

Maximum infusion rate:

Symptomatic hypokalaemia can be corrected at a maximal rate of 1 mmol/kg body weight per hour with a maximum rate of 20 mmol/h.

Potassium supplementation as part of parenteral nutrition:

Recommended maximum daily dose for potassium supplementation as part of parenteral nutrition (in mmol/kg body weight)

Period	Term neonates	Preterm neonates	
		<1500 g	>1500 g
1 st postnatal week		0 – 2.0	
1 st month of life prior to stable growth	1.0 – 3.0	1.0 – 2.0	1.0 – 3.0
1 st month of life with stable growth	1.5 – 3.0	2.0 – 5.0	

Children and infants after the first month of life must not receive more than 3 mmol per kg body weight per day.

Other special patient groups

Changes in acid-base balance affect plasma concentrations. The demand of potassium is increased in compensation of ketoacidosis in diabetic patients and when glucose/insulin is given.

Method of administration

Intravenous use (see section 4.4).

Only to be administered by infusion after dilution in suitable infusion solutions.

The potassium concentration in the infusion solution should normally not exceed 40 mmol/ per litre.

If serum potassium levels in adults are below 2 mmol/ per litre the potassium concentration in the infusion solution may be as high as 80 mmol/ per litre.

For instructions on dilution of the medicinal product before administration, see section 4.4 and 6.6.

As a matter of principle, infusion pumps should be used for the infusion of potassium in the setting of correction therapy.

4.3 Contraindications

Potassium Chloride 15% w/v must not be administered in case of:

- hyperkalaemia.
- hyperchloreaemia.

4.4 Special warnings and precautions for use

Potassium Chloride 15% w/v should only be administered with caution in the presence of:

- Cardiac disease Disorders associated with potassium retention such as impaired renal function, Addison's disease, sickle cell anaemia. Treatment of patients with severe renal impairment and patients on dialysis must be consulted with nephrologist.
- Concurrent treatment with potassium-saving diuretics, Angiotensin II receptor antagonists, ACE inhibitors or potentially nephrotoxic medicinal products (nonsteroidal anti-inflammatories etc.), see also section 4.5.

- shock
- Extensive tissue destruction (e.g. burn injuries)
- hyperkalaemic familial periodic paralysis

Sudden discontinuation of potassium administration may be followed by marked hypokalaemia, which may lead to increased toxicity of cardiac glycosides taken concomitantly.

Initial potassium replacement therapy must not include glucose infusions, because glucose may cause a further decrease in the plasma-potassium concentration.

ECG monitoring should be available.

There are typical changes in the ECG when the potassium balance is disturbed (hypo- or hyperkalaemia). However, there is no linear relationship between the ECG changes and the concentration of potassium in the blood.

Refeeding syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome. Refeeding syndrome consists of hypophosphatemia which is often accompanied by hypokalaemia, hypomagnesaemia, fluid retention and hyperglycaemia. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Clinical monitoring should include checks of the serum electrolyte levels and the acid-base balance.

It must be made absolutely sure that the solution is administered intravenously, because paravenous administration may cause tissue necrosis.

Elderly patients:

Elderly patients, who are more likely to suffer from cardiac insufficiency and renal impairment, should be closely monitored during treatment, and the dosage should be carefully adjusted.

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Date _____ Signature _____

Name in capital letters _____



- **Suxamethonium** (a muscle relaxing agent used in general anaesthesia):

Giving potassium together with this may also lead to very high blood potassium levels. This may affect your heart rhythm.

Pregnancy and breast-feeding

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

Pregnancy

Up to now there are no reports about damaging effects or risks associated with the use of this medicine in pregnant women.

Your doctor will administer potassium chloride to you only with caution and when clearly needed.

Breast-feeding

Potassium chloride concentrate for infusion may be used during breast-feeding.

Driving and using machines

This medicine has no influence on the ability to drive and use machines

3. How to use Potassium Chloride 15% w/v

Potassium Chloride 15% w/v is administered to you after dilution in a suitable solution. It is given through a cannula or small tube into a vein (intravenous infusion).

Dosage

The amount you are to receive is calculated by your doctor, based on your blood electrolyte values, your acid-base balance, your age and your individual requirements.

If you use more Potassium Chloride 15% w/v than you should

It is unlikely that you will ever receive too much of the medicine. Your doctor or healthcare professional will monitor the application.

Symptoms

Overdose may lead to abnormally high potassium levels with the adverse effects listed below. Adverse effects are more likely to occur when you suffer from a shift of your blood to the acidic side (acidosis) or disorders of your kidneys.

Heart and circulation:

- slow heartbeat or even heart stoppage
- changes in the electrocardiogram
- drop of blood pressure
- re-distribution of circulating blood from limbs to head and trunk

Muscles and nerve system:

- weakness
- fatigue
- states of confusion
- heaviness of limbs
- muscle twitching
- loss of feeling
- paralysis

Treatment

If an overdose occurs the infusion will be stopped immediately and your doctor will give you any necessary treatment.

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

4. Possible side effects

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

The following side effects may be serious. If any of the following side effects occur, consult a doctor immediately.

- accumulation of acidic substances in the blood (acidosis) (frequency not known)
- abnormally high chloride blood levels (hyperchloraemia) (frequency not known)
- irregular heart beat (cardiac arrhythmia, the result of abnormally high administration rates) (frequency not known)

Other side effects

- feeling sick (nausea) (frequency not known)
- reactions at the injection site, including local pain, irritation or inflammation of veins (thrombophlebitis) and escape of fluid into the tissue (extravasation) (frequency not known)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly 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 15% w/v

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

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

Do not store above 25°C.

Only to be used if the solution is clear, colourless and the container and its closure are undamaged.

The medicine is supplied in single-use containers. After use, throw away the container and any unused content.

6. Contents of the pack and other information

What Potassium Chloride 15% w/v contains

- The active substance is potassium chloride
 - 1 ml solution contains 150 mg potassium chloride corresponding to 2 mmol potassium and 2 mmol chloride
 - One 10 ml ampoule contains 1.50 g potassium chloride
- The other ingredient is water for injections

What Potassium Chloride 15% w/v looks like and contents of the pack

Potassium Chloride 15% w/v is a concentrate for the production of a solution for infusion. It must be diluted before use and is administered by an intravenous drip.

It is a clear, colourless aqueous solution.

Potassium Chloride 15% w/v is available in

- Polyethylene plastic ampoules, contents: 10 ml in packs of 20 x 10 ml

Marketing Authorisation Holder and Manufacturer

PA Holder:

B. Braun Medical Ltd.,
3 Naas Road Industrial Park,
Dublin 12, Ireland

PA Number:

PA0179/030/002

Manufacturer:

B. Braun Melsungen AG,
Carl-Braun-Straße 1, D-34212 Melsungen, Germany

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The following information is intended for healthcare professionals only:

For complete information on this medicinal product please refer to the summary of product characteristics.

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4.5 Interaction with other medicinal products and other forms of interaction

• Cardiac glycosides

An increase in the extracellular potassium concentration reduces the effect of cardiac glycosides, a decrease leads to an intensification of the arrhythmogenic effect of cardiac glycosides.

• Medicinal products reducing potassium excretion

These include:

- potassium saving diuretics (e.g. triamterene, amiloride, spironolactone)
- Angiotensin II receptor antagonists
- ACE inhibitors
- tacrolimus
- ciclosporin
- non-steroidal anti-inflammatory drugs
- peripheral analgesics
- heparin

Severe hyperkalaemia adversely affecting heart rhythm can result when these drugs are administered concurrently with potassium chloride.

• Medicinal products increasing potassium excretion

ACTH, corticosteroids and loop diuretics can increase the renal elimination of potassium.

• Suxamethonium

Severe hyperkalaemia, with adverse effect on the heart rhythm, can also occur when suxamethonium and potassium are administered concurrently.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Potassium Chloride Concentrates in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

On the basis of known physiological effects of potassium, no adverse effects on the unborn are expected of a normalisation of an abnormal serum potassium concentration. Too high or too low potassium levels can however be detrimental to maternal and foetal cardiac function.

The product should be used only when clearly needed and after carefully weighing out expected benefits against possible risks.

Lactation

Potassium Chloride is excreted in human milk. However, from a normalisation of potassium in the blood no adverse effect is expected on the potassium level in breast milk. Potassium chloride concentrate for infusion - if used according to the directions given - may therefore be used during lactation.

Fertility

No data available

4.7 Effects on ability to drive and use machines

Potassium Chloride 15% w/v has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are listed according to their frequencies as follows:

Very common:	(≥ 1/10)	
Common:	(≥ 1/100	to < 1/10)
Uncommon:	(≥ 1/1,000	to < 1/100)
Rare:	(≥ 1/10,000	to < 1/1,000)
Very rare:	(< 1/10,000)	
Not known	(Frequency cannot be estimated from the available data)	

Metabolism and nutrition disorders

Not known: Acidosis, hyperchloraemia

Cardiac disorders

Not known: Too rapid infusion may provoke cardiac arrhythmia.

Gastrointestinal disorders

Not known: Nausea

General disorders and administration site conditions

Not known: Local reactions at the site of administration, including local pain, vein irritation, thrombophlebitis and extravasation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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

4.9 Overdose

Symptoms

Overdose may cause hyperkalaemia, in particular in the presence of acidosis or kidney insufficiency.

The symptoms of hyperkalaemia are primarily cardiovascular disorders. They may include bradycardia, AV blockade, ventricular fibrillation and cardiac arrest. In the ECG there are high, sharp, symmetrical T-waves and, at very high potassium levels, broadening of the QRS complex. The vascular effects are hypotension and centralisation.

The neuromuscular symptoms include fatigue, weakness, states of confusion, heaviness of limbs, muscle twitching, paraesthesia, and ascending paralysis.

Plasma potassium concentrations of 6.5 mmol/l or more are dangerous, over 8 mmol/l often lethal.

Treatment

The first measure is immediate stop of infusion.

Further corrective measures include slow intravenous administration of 10 % calcium gluconate, infusion of glucose together with insulin, increase of diuresis, oral or rectal administration of cation exchangers, correction of acidosis, if necessary.

In severe cases haemodialysis may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: IV solution additives - electrolytes

ATC code: B05X A01

Mechanism of action

Potassium is the most important cation of the intracellular space, approx. 98 per cent of the organism's total potassium is located there.

Potassium is involved in electrochemical processes of cells and in carbohydrate and protein metabolism.

Potassium deficiency may be caused by increased renal excretion, increased gastrointestinal losses, e.g. by vomiting or diarrhoea, or through fistulae, by increased intracellular uptake, e.g. during therapy of acidosis or therapy with glucose and insulin, or by insufficient potassium intake

Hypokalaemia is accompanied by muscle weakness, atony of gastro-intestinal smooth muscles (constipation up to paralytic ileus), loss of capability of kidneys to concentrate urine, ECG alterations and cardiac arrhythmia.

5.2 Pharmacokinetic properties

Absorption

As the medicinal product is administered intravenously, its bio-availability is 100 per cent.

Distribution

The distribution of potassium follows the normal physiological pathways of potassium metabolism.

The plasma potassium concentration is closely related to the acid-base balance. Alkalosis is often accompanied by hypokalaemia and acidosis by hyperkalaemia. Normal plasma potassium concentrations in acidosis indicate potassium deficiency.

The intracellular potassium concentration is approx. 140-150 mmol/l. The normal potassium serum concentration is between 3.5 and 5 mmol/l.

Elimination

Potassium is mainly excreted into the urine (about 90 per cent) and about 10 per cent are excreted via the gastrointestinal tract.

5.3 Preclinical safety data

Non-clinical data are insufficient. If electrolytes are kept within physiological range, toxic effects are not expected.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

Unopened: 3 years.

After first opening the container:

To be added to diluent immediately after opening the container. See also section 6.6.

Shelf life after dilution according to directions:

Chemical and physical in-use stability of dilutions in 0.9% w/v Sodium Chloride, 5% w/v Glucose and 10% w/v Glucose has been demonstrated for 24 hours at room temperature (15 - 25°C).

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 and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not store above 25°C.

For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Supplied in round or oval polyethylene ampoules (Mini-Plasco®) containing 10ml of solution, in packs of 20 ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Single-dose container. Discard unused contents.

Only to be used if solution is clear and the container and its closure does not show visible signs of damage.

Must be diluted before use with not less than 500ml of suitable diluent and mixed well. The following infusion solutions can be used as diluents: 0.9% w/v sodium chloride, 5% w/v glucose, 10% w/v glucose, compound sodium lactate solution. Potassium Chloride 15% w/v Concentrate for Solution should only be added immediately before setting up the infusion and strictly aseptic technique should be observed. The infusion bottle should then be gently shaken.

7 MARKETING AUTHORISATION HOLDER

B. Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA0179/030/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 November 1991

Date of last renewal: 26 November 2006

10 DATE OF REVISION OF THE TEXT

November 2017

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