1. NAME OF THE MEDICINAL PRODUCT

Kay-Cee-L Syrup

Potassium Chloride 7.5% w/v Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium chloride 7.5% w/v (equivalent to 1 millimole of potassium per ml)

Excipients with known effect: contains 40% w/v sorbitol, 0.002% w/v carmoisine (E122), 0.05% w/v parahydroxybenzoates (methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214) and propyl parahydroxybenzoate (E216)), sodium benzoate (E211) and propylene glycol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear, red, slightly viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of hypokalaemia and potassium deficiency of renal and extrarenal origin.

4.2 Posology and method of administration

Posology

The dosage of Potassium Chloride 7.5% w/v Syrup depends on the cause, degree, and duration of potassium depletion, and should be adjusted accordingly.

Adults: 10 - 50 mL/day in divided amounts after food is usually an adequate dosage.

Elderly: No special dosage adjustment is usually necessary, but concurrent renal insufficiency should be taken into account, and serum potassium levels should be monitored if clinically necessary with dosage adjusted according to response.

Children: As directed by the clinician.
Up to 1 year: The usual dose is 0.5 - 0.75 mL/kg body weight/day in divided amounts after food.
Aged 1 to 12 years: The usual dose is 0.5 - 1.0 mL/kg body

weight/day in divided amounts after food. The dose should be administered using a graduated dropper.

Method of administration
For oral use.

4.3 Contraindications

- Hypersensitivity to the active substance or any of the excipients listed in section 6.1
- Advanced, severe renal failure or impaired renal function with oliguria
- Inadequately treated Addison's disease
- Acute dehydration
- Hyperkalaemia from any cause and conditions involving extensive cell destruction (e.g. severe burns)
- Crush injuries

4.4 Special warnings and precautions for use

Periodic evaluation of the patient's clinical status, serum electrolytes and the ECG should be carried out when replacement therapy is undertaken. This is particularly important in patients with cardiac disease and in those receiving digitalis. Care should be taken to avoid dosage in excess of requirements for patients with impaired renal function.

Oral potassium should be prescribed with caution in patients with a history of peptic ulcer.

Potassium chloride preparations, alone or in combination with other medications, may induce ulceration, haemorrhage or stricture formation in the gastrointestinal tract, in particular the lower oesophagus and the small bowel. This possibility is increased in patients with local disorders of the gastrointestinal tract, with cardiovascular disease, or in those on prolonged therapy. Symptoms or signs suggesting ulceration or obstruction should be regarded as reasons to discontinue medication. Potassium salts should only be administered with extreme caution to patients with renal dysfunction or hepatic disease because of the risk of hyperkalaemia. Potassium supplements should be used with caution in patients who are receiving medications that may increase plasma potassium levels.

Some patients may develop potassium depletion despite the use of potassium supplements particularly in digitalised patients, or those with hepatic ascites. Monitoring of serum potassium is particularly necessary in patients with renal or cardiac diseases, especially the elderly.

Caution is also necessary in patients receiving potassium-sparing diuretics and ACE-inhibitors, and in patients with myotonia congenita or severe haemolysis. In

patients with acidosis, the acid-base balance should be monitored. In patients with hypertension, it should be remembered that correction of hypokalaemia may lower blood pressure.

This medicine contains 1 mmol potassium per ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains sorbitol and may cause gastrointestinal discomfort and mild laxative effect. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicine.

This medicine contains carmoisine (E122) which may cause allergic reactions.

This medicine contains parahydroxybenzoates (E214, E216 and E218) which may cause allergic reactions (possibly delayed).

This medicine contains sodium benzoate (E211). Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains propylene glycol. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates.

4.5 Interaction with other medicinal products and other forms of interaction

Hyperkalaemia can result from the concurrent use of potassium supplements with ACE inhibitors, aldosterone antagonists, angiotensin II receptor antagonists, ciclosporin, potassium sparing diuretics and tacrolimus. The risk of hyperkalaemia is increased in patients taking potassium supplements and digoxin, particularly in cases of acute digoxin overdosage. The incidence of hyperkalaemia is increased by renal impairment.

4.6 Fertility, pregnancy and lactation

No clinical problems have been encountered during pregnancy and lactation. Nevertheless, Potassium Chloride 7.5% w/v Syrup should not be used during pregnancy or by nursing women unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

In rare cases, oral potassium may invoke nausea, vomiting, diarrhoea and abdominal cramps. Potassium chloride, alone or in combination with other medications, may induce ulceration in the gastrointestinal tract, in particular the lower oesophagus and the small bowel. This possibility is increased in patients with local disorders of the

gastrointestinal tract with cardiovascular disease or in those on prolonged therapy. If there are any signs of gastric irritancy, Potassium Chloride 7.5% w/v Syrup, in common with all other potassium salts, should be given after food. Symptoms or signs suggesting ulceration or obstruction of the tract should be regarded as reason to discontinue medication. Hyperkalaemia associated with excessive intake of potassium salts will rarely occur with Potassium Chloride 7.5% w/v Syrup which normally acts as an emetic after inadvertent high dosage. Ingestion of potassium chloride may induce hyperkalaemia in patients with familial hyperkalaemic periodic paralysis. A moderate hyperkalaemia may be asymptomatic; if suspected reference to the section on overdosage is recommended.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Hyperkalaemia. Poisoning is usually minimal below 6.5 mmol per litre but may be severe above 8 mmol per litre. However, comparatively low doses may cause adverse effects when excretion is delayed as in renal insufficiency. The absolute toxicity is dependent on other electrolytes and acid-base levels.

Hyperkalaemic symptoms include paraesthesia of the extremities, listlessness, mental confusion, weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac arrest.

Hyperkalaemia is often asymptomatic. However, increasing serum potassium levels can be detected by changes in the ECG; initially the appearance of tall, peaked T waves, followed by a widening of the QRS complex bending into the abnormal T waves. P-wave voltage decreases and the PR interval is prolonged.

Severe cardiac toxicity may be treated with calcium gluconate (10-20ml of a 10% injection given over 1-5 minutes with ECG monitoring). The effect may be transient and the injection may need to be repeated.

Raised serum potassium levels respond to administration of dextrose (300-500ml/hr of 10 or 25% solution), dextrose and insulin (as for dextrose with 10 units of insulin per 20g dextrose), or sodium bicarbonate solution.

Cation exchange resins may be used, or in severe cases peritoneal dialysis or haemodialysis may be necessary.

Caution should be exercised in patients who are digitalised and who may experience acute digitalis intoxication in the course of potassium removal.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Potassium ATC code: A12BA01.

The potassium ion is essential to the maintenance of body function, being involved in the synthesis of protein, metabolism of carbohydrate and storage of energy reserves. Potassium, the major intracellular cation, plays a significant part in control of osmotic pressure and is an essential activator in a number of enzymatic reactions. It interacts with sodium in the operation of the transmembrane pump and at the site of exchange in the kidney, exchanges with sodium ion to maintain body homeostasis. The potassium concentration of body fluids has an important influence on the excitability of both skeletal and cardiac muscle and on the structure and function of the kidneys. Disturbances in potassium equilibrium produce a wide range of disorders and the clinically deleterious consequences of hypokalaemia and potassium deficiency are substantially monographed and referenced in the world literature.

A close relationship between potassium ion and magnesium ion has also been noted; a deficit in one ion has been associated with low levels of the other.

The diet of a healthy adult will provide an adequate intake of potassium (considered to be 20.5 to 33.3 mmol potassium daily) from a total intake of 60-100 mmol potassium. Total body potassium in an adult is about 3,500 mmol depending on the non-fat body tissues. A deficient intake or failure to conserve potassium leads to symptoms of hypokalaemia.

5.2 Pharmacokinetic properties

The pharmacokinetics of potassium are substantially monographed and referenced.

Unless a deficiency is present, requiring a supplement, sufficient potassium is Taken into the body through the daily diet.

Ingested potassium chloride is generally readily absorbed from the gastrointestinal tract. Potassium enters the intracellular fluid to maintain a concentration of about 150 mEq/l and the normal range of concentration of potassium in the plasma is considered to be 3.5 - 5 mEq/l. The mechanisms underlying the transport of potassium in the human small bowel have shown that it occurs by passive processes in both the jejunum and ileum, and that in the jejunum solvent drag plays a significant part in potassium absorption.

As Potassium Chloride 7.5% w/v Syrup contains approximately 20 times the concentration in milliequivalents as normal plasma, it might be expected that initial absorption would be very rapid. It is known however that for solutions of potassium chloride the bowel or the small intestine responds by thickening of its secretion. In Potassium Chloride 7.5% w/v Syrup, the high concentration of sorbitol also produces an osmotic effect on the bowel producing secretion. This results in a dilutional effect on the potassium chloride thus slowing absorption. Furthermore, the recommended administration of Potassium Chloride 7.5% w/v Syrup after meals again dilutes the

dose volume in the concomitant intestinal secretion; absorption of the potassium chloride component therefore takes place over several hours when taken after meals.

Excretion of potassium is mainly by the distal tubules of the kidney, by the faeces (5 to 10 mmol/day) and a smaller amount in perspiration.

Metabolic, drug induced, or dietary deficiencies in potassium intake may require administration of a supplement

5.3 Preclinical safety data

Potassium Chloride 7.5% w/v Syrup contains potassium chloride (which is the subject of pharmacopoeial monographs). No preclinical data are provided as potassium chloride is a well-established active ingredient. The physiological, pharmacological and clinical toxicity of potassium salts are well documented and limited animal data are therefore available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium Chloride 7.5% w/v Syrup contains the following excipients:
sorbitol,
carmoisine (E122),
wild cherry flavour F617,
sodium benzoate,
saccharin sodium,
methyl parahydroxybenzoate (E218),
ethyl parahydroxybenzoate (E214),
propyl parahydroxybenzoate (E216),
propylene glycol and
purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

Sealed bottles: 36 months. After opening: 8 weeks.

6.4 Special precautions for storage

Potassium Chloride 7.5% w/v Syrup should be stored below 25°C.

6.5 Nature and contents of container

150ml or 500ml glass bottles

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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Ruislip, Middlesex,
HA4 0NU,
UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 39307/0145

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 December 1996

10 DATE OF REVISION OF THE TEXT

15/05/2026