

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kay-Cee-L Syrup 7.5% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

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

Excipients: contains 40% w/v sorbitol, 0.002% w/v carmoisine (E122) and 0.05% w/v parahydroxybenzoates.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution.

A clear, red, slightly viscous oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Route of administration: oral.

The dosage of Kay-Cee-L 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.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

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. However, the risk of such events is much lower with a syrup dose form such as Kay-Cee-L Oral Solution than with potassium chloride tablets. Nevertheless, 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 taking potassium-sparing diuretics (e.g., spironolactone, triamterene or amiloride) or Angiotensin Converting Enzyme (ACE) inhibitors because of the risk of hyperkalaemia.

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.

In cases of metabolic acidosis associated with hypokalaemia, an alkaline potassium salt (potassium bicarbonate) rather than potassium chloride should be used.

Kay-Cee-L Syrup contains sorbitol and may have a mild laxative effect. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Carmoisine (E122) and parahydroxybenzoates (E214, E216 and E218) may cause allergic reactions (possibly delayed in the case of the parahydroxybenzoates).

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

Kay-Cee-L Oral Solution should not be used during pregnancy 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. 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 Kay-Cee-L 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.

4.9 Overdose

High doses taken inadvertently will act as an emetic. In rare cases where an emetic response is not effected, symptoms of overdosage include: asthenia, hypotension, mental confusion, paraesthesia, cardiac arrhythmias and characteristic ECG changes.

Antidote: hyperkalaemia should be treated with an intravenous infusion of insulin and dextrose. In any case of severe hyperkalaemia, calcium gluconate should be given intravenously (10 - 20 mL of a 1% solution) to stabilise the myocardium before reducing the serum potassium level. Mild hyperkalaemia should be treated by having the patient drink a large volume of water or by administration of oral calcium resonium.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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. 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.

5.2 Pharmacokinetic properties

The pharmacokinetics of potassium are substantially monographed and referenced.

Ingested potassium chloride is generally readily absorbed from the gastrointestinal tract. 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 Kay-Cee-L 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 respond by thickening of its secretions. In Kay-Cee-L 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 Kay-Cee-L 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.

5.3 Preclinical safety data

No preclinical data are provided as potassium chloride is a well-established active ingredient.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)
Carmoisine (E122)
Wild cherry flavour F617
Sodium benzoate
Saccharin sodium
Methyl parahydroxybenzoate (E218)

Ethyl parahydroxybenzoate (E214)
Propyl parahydroxybenzoate (E216)
Propylene glycol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Sealed bottles: 3 years
After opening: 8 weeks

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Amber glass bottles with polypropylene screw caps containing 500 ml.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Geistlich Sons Ltd.
1st Floor
Thorley House
Bailey Lane
Manchester Airport
Manchester M90 4AB
United Kingdom

8 MARKETING AUTHORISATION NUMBER

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