PRESCRIBING INFORMATION

K-10

(Potassium Chloride Oral Solution, 10% USP)

POTASSIUM REPLACEMENT THERAPY

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PRESCRIBING INFORMATION

NAME OF DRUG
K-10

(Potassium Chloride Oral Solution, 10% USP)

THERAPEUTIC CLASSIFICATION

Potassium Replacement Therapy

INDICATIONS AND CLINICAL USE

The prevention and treatment of hypokalemic states which may occur in conjunction with diuretic therapy, digitalis intoxication, corticosteroid therapy, inadequate dietary intake, loss of potassium due to vomiting and diarrhea, hypochloremic alkalosis, diabetic acidosis, and familial periodic paralysis as well as other causes.

Pediatrics
Safety and effectiveness in children has not been established, potassium chloride is therefore not recommended for pediatric use.

GERIATRICS
Potassium chloride should be used with special caution and with frequent serum potassium monitoring in elderly patients due to increased risk of hyperkalemia.

CONTRAINDICATIONS

Potassium chloride is contraindicated in patients with: Adrenal insufficiency (Addison's disease), conditions involving extensive cell destruction (e.g. severe burns), congenital paramyotonia, acute dehydration, exacerbations of peptic ulcer disease, gastrointestinal bleeding (see WARNINGS AND PRECAUTIONS), hyperkalemia, hyperkalaemic periodic paralysis, hypersensitivity to any of the preparation's ingredient, hyporeninaemic hypoaldosteronism, metabolic acidosis (due to uncontrolled diabetes), renal failure, concomitant treatment with a potassium-sparing diuretic (eg. spironolactone, triamterene, amiloride) alone or in combination with a saluretic-diuretic agent (see INTERACTIONS)

INTERACTIONS

Potassium serum concentration should be periodically measured during concomitant administration of drugs which interact with this product. Increase of potassium serum concentration may occur when potassium chloride is used simultaneously with: potassium sparing diuretics, angiotensin-converting-enzyme (ACE) inhibitors, angiotensin-II receptor blockers, cyclosporin, nonsteroidal anti inflammatory drugs - NSAIDS (e.g. indomethacin), heparin, cardiac glycosides, β-adrenolytics and other potassium-containing products (see CONTRAINDICATIONS).

Potassium-sparing diuretics
Concomitant use of potassium chloride and potassium-sparing diuretics such as amiloride, , spironolactone, triamterene (alone or in combination) is contraindicated (see CONTRAINDICATIONS). Risk of potentially lethal hyperkalemia is particularly high in patients with kidney failure (added effects of potassium-sparing diuretics).

ACE inhibitors
Concomitant use of potassium chloride with angiotensin-converting-enzyme (ACE) inhibitors is not recommended except in the case of hypokalemia. Concomitant use of these medicinal products induces a risk of potentially lethal hyperkalemia particularly in patients with kidney failure.

Cardiac glycosides
Special caution should be used in concomitant use of the potassium chloride and cardiac glycosides. Hyperkalemia may cause atrioventricular conductivity disorders.

Non-steroid anti-inflammatory drugs
Special caution should be used in concomitant use of the potassium chloride and non-steroid anti-inflammatory drugs. Non-steroid anti-inflammatory drugs may cause hyperkalemia. During concomitant treatment with these drugs control of serum potassium concentration is necessary.

Direct renin inhibitors, proton pump inhibitors
Direct renin inhibitors (e.g. aliskerin), proton pump inhibitors can cause hyperkalemia when used concomitantly with potassium chloride. Thus, caution should be exercised in their concomitant use.s

WARNINGS AND PRECAUTIONS

Treatment Monitoring
Potassium chloride must be administered cautiously, since the degree of deficiency or the ideal daily dosage often is not accurately known. Excessive dosage may give rise to potassium intoxication. Frequent checks of the clinical status of the patient, and the periodic ECG and/or serum potassium levels should be made before and during treatment.

Potassium intoxication may result from overdosage of potassium or from therapeutic dosage in conditions stated under CONTRAINDICATIONS.

Ability to perform tasks that require judgement, motor or cognitive skills
The drug has no effect on the ability to drive vehicles and operate machinery.

Cardiac
This drug should be used with caution in the presence of cardiac disease.

Fertility
There are no relevant data available.

Gastrointestinal
Potassium chloride should be withdrawn in the presence of severe abdominal pain, hematemesis and black feces (see CONTRAINDICATIONS). Potassium chloride, alone or in combination with other medications may induce ulceration in the gastrointestinal tract, in particular the lower esophagus and small bowel. This possibility is increased in patients with local, functional or mechanical disorders of the gastrointestinal tract, with cardiovascular disease, or in those on prolonged therapy or receiving anticholinergics. Symptoms or signs suggesting ulceration or obstruction of the tract should be regarded as reasons to discontinue medication immediately.

Lactation
The drug may be given to breast-feeding women only if in the physician's judgement the benefit for the mother outweighs the potential risk to the fetus.

Pregnancy
The drug may be given to pregnant women only if in the physician's judgement the benefit for the mother outweighs the potential risk to the fetus. There is no data on the risk for the fetus in humans and animals, as no properly controlled clinical trials have been conducted.

Other
In some patients, diuretic induced magnesium deficiency will prevent restoration of intracellular deficits of potassium so that hypomagnesaemia should be corrected at the same time as hypokalemia.

Special Populations

Pediatrics
Safety and effectiveness in children has not been established, potassium chloride is therefore not recommended for pediatric use.

GERIATRICS
Potassium chloride should be used with special caution and with frequent serum potassium monitoring in elderly patients due to increased risk of hyperkalemia.

Hepatic impairment
No studies have been performed in hepatically impaired patients. However, potassium chloride should be given with caution due to increased likelihood of electrolyte disturbances in patients with hepatic impairment (see CONTRAINDICATIONS).

Renal impairment
Potassium chloride is contraindicated in patients with renal failure (see CONTRAINDICATIONS and INTERACTIONS).

ADVERSE REACTIONS

Cardiac disorders
Arrhythmia, atrioventricular conduction disorders.

Gastrointestinal disorders
Nausea, vomiting, flatulence, abdominal pain, abdominal discomfort, diarrhea, burning sensation in the stomach and esophagus, constipation, small intestine erosions, obstruction, hemorrhage and gastroduodenal ulceration.

The risk of gastroduodenal ulceration increases at high doses of potassium chloride. Cases of small intestine ulceration have been reported.

Metabolism and nutrition disorders
Hyperkalemia (with risk of sudden death). Hyperkalemia should be prevented by monitoring potassium levels (see WARNINGS AND PRECAUTIONS).

Skin and subcutaneous tissue disorders
Rash, pruritus, urticaria

OVERDOSAGE

Symptoms
The severity of symptoms depends on the severity of hyperkalemia. The symptoms of potassium chloride overdosage may include cardiovascular events (hypotension, shock, ventricular arrhythmias, bundle-branch block, and ventricular fibrillation leading possibly to cardiac arrest) and neuromuscular events (paraesthesiae, convulsions, areflexia, flaccid paralysis of striated muscle leading possibly to respiratory paralysis). Beside elevation of serum potassium concentration, typical ECG changes are also encountered (increasing amplitude and peaking of T waves, disappearance of P wave, widening of QRS complex and S-T segment depression).

Treatment
The drug should be withdrawn if overdose symptoms occur. Considerable overdose requires hospitalization.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DOSAGE AND ADMINISTRATION

Adults: Take as directed by a physician. One tablespoonful (15 mL) twice daily, dissolved completely in 100-250 mL of cold water, juice or other liquid. Take with food or immediately after meals and drink slowly (to minimize gastrointestinal irritation and prevent too rapid absorption). Deviation from this recommendation may be indicated since no average total daily dose can be defined but must be governed by close observation for clinical effects. In determining dosage, it has to be remembered that fruits, vegetables and their juices contain potassium. Patients should be cautioned to follow directions explicitly in regard to dilution of K-10 to prevent gastrointestinal injury.

Children: There are no relevant data available.

Elderly: Potassium chloride should be used with special caution in elderly patients.

Renal impairment: Potassium chloride is contraindicated in patients with renal failure (see CONTRAINDICATIONS and INTERACTIONS).

Hepatic impairment: There are no relevant data available.

STORAGE AND STABILITY

Store between 15°C - 25°C. Do not freeze.

DOSAGE FORMS, COMPOSITION AND PACKAGING

K-10 (potassium chloride oral solution, 10% USP) is a clear, colourless liquid with a characteristic lemon taste.

Each tablespoon (15 mL) contains potassium chloride 1.5 g (supplying 20 mEq of elemental potassium) and the following non-medicinal ingredients: calcium cyclamate, citric acid, glycerin, lemon flavour, orange flavour, purified water and sodium benzoate.

Available in bottles of 500 mL.

NON-CLINICAL INFORMATION

Preclinical data do not support a special hazard for humans based on conventional studies of acute toxicity, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

The acute and repeated-dose oral toxicity of potassium chloride (KCl) in animals is low gastrointestinal irritant effects have been observed in rhesus monkeys at high oral dosages of potassium chloride. Some positive results in in vitro genotoxicity assays were attributed to very high concentrations of KCl. Carcinogenicity studies in rats administered KCl in-feed were negative. Limited information from oral developmental studies in rodents indicates there is no ill effect on offspring. There is no evidence from animal experiments that oral KCl exerts any teratogenic effects or reproductive toxicity which would be relevant to man.

CONSUMER INFORMATION

K-10
(Potassium Chloride Oral Solution, 10% USP)

This leaflet is a part of "Prescribing Information" for **K-10** and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about K-10. Contact your doctor or pharmacist if you have any questions about this product.

ABOUT THIS MEDICATION

What the medication is used for:

Potassium replacement therapy is used for the prevention and treatment of low amounts of potassium in the blood.

What it does:

K-10 helps restore or keep the proper amount of potassium in your body. Levels of potassium can be low as a result of a disease or from taking some medicines, the type of food you're eating, or after a prolonged illness with diarrhea or vomiting.

When it should not be used:

You should not use K-10 if you:

- have a condition in which your adrenal glands do not make enough of some hormones (Addison's disease)
- have severe burns or other tissue damage
- have genetic muscular conditions (congenital paramyotonia)
- are dehydrated
- have peptic ulcer disease
- have gastrointestinal bleeding (blood in stool)
- have high levels of potassium in your blood (hyperkalemia)
- have muscle weakness or muscle spasms (hyperkalaemic periodic paralysis)
- have metabolic acidosis (due to uncontrolled diabetes)
- have kidney failure
- have had allergic reactions to K-10 or potassium chloride or any of the ingredients in K-10
- have low levels of an enzyme called renin and a horrmone called aldosterone which normally help to control your blood pressure (hyporeninaemic hypaldosteronism)
- are taking "water pills" (potassium-sparing diuretics) such as spironolactone, triamterene, or amiloride.

What the medicinal ingredient is:

Each tablespoon (15 mL) contains 1.5 g potassium chloride.

What the nonmedicinal ingredients are: Calcium cyclamate, citric acid, glycerin, lemon flavour, orange flavour, purified water and sodium benzoate.

What dosage forms it comes in:

K-10 is a clear, colourless liquid with a lemon taste. It comes in 500 mL bottles.

WARNINGS AND PRECAUTIONS

BEFORE you use K-10 talk to your doctor or pharmacist if you:

- have kidney, liver or heart conditions
- are 65 years old or older
- have severe abdominal pain, are vomiting blood or pass black stool
- are pregnant or breastfeeding

Talk to your doctor if you are taking any of these medications:

- angiotensin-converting-enzyme (ACE) inhibitors such as enalapril or lisinopril (used to treat high blood pressure and some heart conditions)
- angiotensin-II receptor blockers such as losartan (used to treat high blood pressure)
- cyclosporin (used to prevent rejection after organ translplantation)
- nonsteroidal anti inflammatory drugs (NSAIDS) such as indomethacin (used to treat pain and inflammation)
- heparin (used to prevent blood clots),
- cardiac glycosides (used to treat heart failure)
- β-blockers or other heart medication
- direct renin inhibitors, proton pump inhibitors (e.g. aliskerin)
- other potassium-containing products

K-10 must be administered cautiously. Excessive dosage may give rise to potassium intoxication.

K-10 is not recommended for use in children. Keep out of reach of children.

INTERACTIONS WITH THIS MEDICATION

Talk to your doctor if you are taking any of these medications:

- angiotensin-converting-enzyme (ACE) inhibitors such as enalapril or lisinopril (used to treat high blood pressure and some heart conditions)
- angiotensin-II receptor blockers such as losartan

(used to treat high blood pressure)
- cyclosporin (used to prevent rejection after organ translplantation)
- nonsteroidal anti inflammatory drugs (NSAIDS) such as indomethacin (used to treat pain and inflammation)
- heparin (used to prevent blood clots),
- cardiac glycosides (used to treat heart failure)
- β-blockers or other heart medication
- direct renin inhibitors, proton pump inhibitors (e.g. aliskerin)
- other potassium-containing products

PROPER USE OF THIS MEDICATION

Usual adult dose:

One tablespoonful (15 mL) twice daily, dissolved completely in 100-250 mL of cold water, juice or other liquid as directed by your doctor. Take with food or immediately after meals and drink slowly.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you accidentally take a larger dose of K-10 (i.e. more drug than recommended by your doctor), you may feel shortness of breath, feel like your heart is beating faster than normal or beating unevenly, feel dizzy or lightheaded, or experience muscle weakness or tingling sensation on your skin.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

• Fast or irregular heartbeat • Dizziness, shortness of breath • Gas, nausea or vomiting, burning sensation in the throat, chest and stomach • Diarrhea, stomach pain, constipation • Muscle weakness, tingling or numbness of the hands and feet, low energy, confusion, cold skin, greyish skin , low blood pressure, muscle weakness or difficulty breathing (symptoms of high potassium in the blood) • Rash, itching	**Discontinue use and consult a health care practitioner if you experience these reactions**

This is not a complete list of side effects. For any unexpected effects while taking K-10*, contact your doctor or pharmacist.*

HOW TO STORE IT

Store K-10 at 15°C to 25°C. Do not freeze.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or

- Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

http://www.gsk.ca or by contacting the sponsor,

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