PRODUCT MONOGRAPH

SLO-POT

Slow-Release Potassium Chloride Tablets

(600 mg)

Potassium Supplement

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(600 mg)

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ACTION:

Potassium ions participate in numerous essential physiological processes including the maintenance of intracellular tonicity, the transmission of nerve impulses, the contraction of cardiac, skeletal, smooth muscle and the maintenance of normal renal function. (See PHARMACOLOGY). Depletion may occur whenever the rate of potassium loss through renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium intake. SLO-POT provides a controlled release, over a period of 4-5 hours, of potassium chloride from a wax matrix, thereby minimizing the possibility of producing high localized concentration of potassium within the gastrointestinal tract.

INDICATIONS:

SLO-POT (potassium chloride) is indicated for the treatment of potassium depletion in patients with hypokalemia and metabolic alkalosis and for the treatment of digitalis intoxication.

SLO-POT is also indicated for the prevention of potassium depletion when the dietary intake of potassium is inadequate for this purpose.

The prophylactic administration of potassium ion may be indicated in patients receiving digitalis and diuretics for the treatment of congestive heart failure and hepatic cirrhosis with ascites. SLO-POT may be indicated in selected hypertensive patients on long-term diuretic therapy, hyperaldosteronism states with normal renal function, the nephrotic syndrome and certain diarrheal states.

CONTRAINDICATIONS:

SLO-POT (potassium chloride) is contraindicated in renal impairment with oliguria or azotemia, untreated Addison's disease, hyperadrenalism associated with adrenogenital syndrome, extensive tissue breakdown as in severe burns, heat cramps, acute dehydration, adynamia episodica hereditaria and hyperkalemia of any etiology.

All solid dosage forms of potassium supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

Wax matrix potassium chloride preparations have been reported to produce esophageal ulceration in certain cardiac patients with esophageal compression due to an enlarged left atrium. SLO-POT is therefore contraindicated in such patients as well as in patients with dysphagia.

WARNINGS:

The administration of potassium salts to patients with impaired mechanisms for excreting potassium, can produce hyperkalemia and cardiac arrest.

This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g. spironolactone or triamterene), since the simultaneous administration of these agents can produce severe hyperkalemia. Hyperkalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium acetate, potassium bicarbonate or potassium citrate.

A probable association exists between the use of coated tablets containing potassium salts, with or without thiazide diuretics, and the incidence of serious small bowel ulceration. Such preparations should be used only when adequate dietary supplementation is not practical and should be discontinued if abdominal pain, distention, nausea, vomiting or gastrointestinal bleeding occurs.

SLO-POT is a wax matrix tablet formulated to provide a controlled rate of release of potassium chloride and thus, to minimize the possibility of a high local concentration of potassium near the bowel wall. While the reported frequency of small bowel lesions is very much less with wax matrix tablets (less than one per 100,000 patient years) than with enteric-coated potassium chloride (40-50 per 100,000 patient years), a few cases associated with wax matrix tablets have been reported.

If severe vomiting, abdominal pain, distention or gastrointestinal bleeding occurs, SLO-POT should be discontinued immediately and the possibility of bowel obstruction or perforation considered.

PRECAUTIONS:

Particularly in the presence of cardiac disease, renal disease or acidosis, the treatment of potassium depletion requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram and the clinical status of the patient.

SLO-POT should be administered with caution in diseases associated with heart block since increased serum potassium may increase the degree of block.

ADVERSE REACTIONS:

Small bowel lesions have been reported following the administration of potassium chloride in slow-release wax matrix tablets. The incidence is much lower than that reported for enteric-coated potassium chloride tablets (See WARNINGS) .

The most common adverse reactions are nausea, vomiting, diarrhea and abdominal discomfort. These symptoms are due to irritation of the gastrointestinal tract and are best avoided by taking the dose with meals, increasing fluid intake when possible or reducing the dose. The most severe adverse effects are hyperkalemia (See WARNINGS) , esophageal and gastrointestinal obstruction, bleeding or perforation (See WARNINGS).

SYMPTOMS AND TREATMENT OF OVERDOSAGE:

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (See CONTRAINDICATIONS AND WARNINGS). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest. Should any of these manifestations occur, the administration of SLO-POT should be immediately discontinued.

Treatment measures for hyperkalemia include the following:
1) elimination of foods and medications containing potassium and of potassium-sparing diuretics;
2) intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10-20 units of insulin per 1,000 mL;
3) correction of acidosis, if present, with intravenous sodium bicarbonate;
4) use of exchange resins, hemodialysis, or peritoneal dialysis;
5) calcium gluconate.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

DOSAGE AND ADMINISTRATION:

The usual dietary intake of potassium by the average adult is 40-80 mEq per day. Potassium depletion sufficient to cause hypokalemia usually requires the loss of 200 or more mEq of potassium from the total body store.

Dosage must be adjusted to the individual needs of each patient. Prevention of hypokalemia: Typically in the range of 20 mEq per day.

Treatment of depletion: Typically in the range of 40 to a maximum of 100 mEq per day.

SLO-POT is preferably administered after meals.

The usual dosage range is 2-6 SLO-POT tablets daily. It is recommended not to exceed 12 tablets daily.

AVAILABILITY:

Each round, dark beige, sugar coated tablet, imprinted ICN S17 contains 600 mg of Potassium Chloride (equivalent to 8 mEq of Potassium).

Available in bottles of 100 and 1000 tablets.

CHEMISTRY:

Potassium Chloride

Molecular Formula: KC1 Molecular Weight: 74.55
K = 42.44%, C1 47.56%.

Description:

SLO-POT tablets are pale orange, sugar coated tablets, containing 600 mg potassium chloride (equivalent to 8 mEq) in a wax matrix.

PHARMACOLOGY:

Potassium is the predominant intracellular cation irvolved in a number of essential physiological processes, including the maintenance of intracellular tonicity and the maintenance of normal renal function.

Potassium ions assume a vital role in the maintenance of electrical excitability of nerve and muscle. Potassium also plays an important role in the genesis and correction of imbalances of acid-base metabolism.

Almost all the dietary potassium is absorbed from the gastrointestinal tract. Potassium is accumulated by cells by an energy-dependent mechanism that extrudes sodium. Potassium is excreted by the kidneys and in normal conditions any amount given in excess of intracellular requirements is rapidly eliminated.

TOXICOLOGY:

Study to evaluate the ulcerogenic effect of potassium chloride in slow-release tablets in comparison with enteric-coated potassium chloride tablets and placebo was conducted in Macaca Assamensis monkeys.

Four groups of monkeys (2 males and 2 females per group) were administered one of the randomly assigned potassium formulations, orally in a divided dose of 6000 mg per day for 4 1/2 days.

Necropsy and microscopic examination of the whole gastrointestinal tract of the two groups of animals which received the slow-release potassium chloride (2 manufacturer's formulation) showed, equivalent mild lymphatic dilations and one incidence of microscopic focal ulceration at the ilial-cecal junction (SLO-POT group) and one mild focal gastric ulceration (SLOW-K group).

The animals which received the placebo showed no significant findings except for an incidental focal area of submucosal hemorrhage in one animal.

Two animals which received the enteric-coated potassium tablets showed on gross and microscopic examination a significant mucosal hemorrhage. Focal ulceration at the i1ia1-cecal junction was also observed.

The remaining two animals in this group had undigested tablets in the lower intestinal tract and thus may have been protected from the effects of ionic potassium.

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