

## **PotbloK**

### **Product Description:**

Each sachet (16 gm) contains Calcium Polystyrene Sulphonate 15 gm.

### **General Information:**

PotbloK (calcium polystyrene sulfonate) is a cation exchange resin prepared in the calcium phase. Each gram of resin has a theoretical in vitro exchange capacity of about 1.3 to 2 millimoles (mmol) of potassium (K<sup>+</sup>). In vivo, the actual amount of potassium bound will be less than this. The sodium (Na<sup>+</sup>) content of the resin is less than 1 mg/g. The calcium content is 1.6 to 2.4 mmol/g. The resin is insoluble in water. Calcium polystyrene sulfonate is not absorbed from the gastrointestinal tract.

### **Indication & Usage:**

PotbloK is indicated in all states of hyperkalemia due to acute and chronic renal failure; examples include use following abortion, complicated labor, incompatible blood transfusion, crush injury, prostatectomy, severe burns, surgical shock, and in cases of severe glomerulonephritis and pyelonephritis.

PotbloK can also be used in patients requiring dialysis. Serum potassium levels in acute renal failure often increases to a higher level before a rise in blood urea indicates the need for hemodialysis. PotbloK can be used to reduce these potassium levels and thereby postpone the need for the use of the artificial kidney machine until other causes make it necessary.

Patients on regular hemodialysis therapy may develop shunt difficulties and under dialysis occurs, resulting in serious hyperkalemia. In these circumstances it is advisable to give the resin to control hyperkalemia during the period of under dialysis. Monitoring serum potassium and calcium levels should be undertaken at regular intervals.

### **Dosage and Administration:**

Treatment with the resin should be given as soon as the serum potassium level rises above 6 mmol/L (23.5 mg per 100 mL). PotbloK is for oral or rectal administration only.

### **Adults, Including the Elderly:**

**a) Oral:** For adults the usual dose is 15 g, 3 or 4 times a day. The resin is given by mouth as a suspension in a little water, or for greater palatability, the resin may be made into a paste with some sweetened vehicle, but not orange juice or other fruit

juices that are known to contain potassium. The amount of fluid usually ranges from 3 to 4 mL per gram of resin. If there is difficulty with swallowing, it may be given through a gastric tube, 2 to 3 mm in diameter.

**b) Rectal:** In cases where vomiting may make oral administration difficult or in patients who have upper gastrointestinal tract problems, the resin may be given rectally as a suspension of 30 g resin in 100 mL of 2% methylcellulose and 100 mL of water, as a daily retention enema. In the initial stages, administration by this route as well as orally may help to achieve a more rapid lowering of the serum potassium level.

#### **Children:**

**a) Oral:** In smaller children and infants correspondingly, smaller doses should be employed by using as a guide a rate of 1mEq of potassium per gram of resin as the basis for calculation. Children should be given 1 g/kg body weight of PotbloK daily in divided doses, in acute hyperkalemia. In maintenance therapy the dose may be reduced to 0.5 g/kg body weight daily in divided doses.

**b) Rectal:** When the resin is refused by mouth it may be given rectally suspended in a proportional amount of 10% dextrose in water, using a dose at least as great as that which would have been given orally.

#### **Neonates:**

Oral administration of PotbloK is contraindicated in neonates. Only rectal administration should be considered. With rectal administration, the minimum effective dosage within the range of 0.5 g/kg to 1 g/kg should be employed, diluted as for adults and with adequate irrigation to ensure recovery of the resin.

#### **Mechanism of action:**

PotbloK acts by a cumulative process throughout the gastrointestinal tract, removing potassium ions which are excreted in the feces.

As the resin passes through the colon, it comes into contact with fluids containing increasing amounts of potassium. In the cecum the concentration of Na<sup>+</sup> and K<sup>+</sup> are similar to those in the small intestine. In the stool water of the sigmoid colon there may be 6-38 mmol/L sodium and 14-44 mmol/L potassium. The result is that potassium is taken up in increasing amounts in exchange for calcium ions. The length of time the resin remains in the body is a decisive factor in its effectiveness. For this reason oral administration is more effective than the use of enemas which should, if possible, be retained for 9 hours. The efficiency of potassium exchange is unpredictably variable. The resin is not selective for potassium.

#### **Pharmacokinetic:**

Pharmacokinetic studies have not been carried out with Calcium polystyrene sulfonate as Calcium polystyrene sulfonate is not absorbed from the GI tract.

#### **Use in Specific Population:**

**Pregnancy:** PotbloK is not absorbed from the gastrointestinal tract. No data are available about the use of polystyrene sulfonate resins in human pregnancy.

**Nursing Mother:** PotbloK is not absorbed from the gastrointestinal tract. No data are available about the use of polystyrene sulfonate resins in human lactation.

**Contraindication:** PotbloK should not be administered to patients with:

- Serum potassium < 5 mmol/L
- Conditions associated with hypercalcemia (e.g. hyperparathyroidism, multiple myeloma, sarcoidosis or metastatic carcinoma)
- A history of hypersensitivity to polystyrene sulfonate resins
- Obstructive bowel disease

### **Warning & Precaution:**

In neonates, PotbloK should not be given by the oral route.

**Gastrointestinal injuries:** Cases of gastrointestinal stenosis, intestinal ischemia, ischemic colitis, rectal haemorrhage, gastrointestinal necrosis and intestinal perforation with fatal outcomes have been reported in association with PotbloK use. The majority of these cases reported the concomitant use of sorbitol. Risk factors for gastrointestinal adverse events were present in many of the cases including prematurity, history of intestinal disease or surgery, hypovolemia, immunosuppressant therapy, severe burns, and renal insufficiency and failure. Concomitant administration of sorbitol is not recommended

### **Drug Interaction**

**Concomitant use not recommended:**

**Orally administered medications:**

**Sorbitol (oral or rectal):** Concomitant administration of sorbitol with PotbloK is not recommended due to cases of intestinal necrosis and other serious gastrointestinal adverse reactions, which may be fatal

**Digitalic drugs:** The toxic effects of digitalis on the heart, especially various ventricular arrhythmias and atrioventricular (A-V) nodal dissociation, are likely to be exaggerated if hypokalemia and/or hypercalcemia develop, even in the face of serum digoxin concentrations in the 'normal range'

**Non-absorbable cation-donating antacids and laxatives:** Systemic alkalosis has been reported after cation-exchange resins were administered orally in combination with non-absorbable cation-donating antacids and laxatives such as magnesium hydroxide and aluminum carbonate.

**Aluminum hydroxide:** Intestinal obstruction due to concretions of aluminum hydroxide has been reported when aluminum hydroxide was combined with the resin

**Lithium:** Possible decrease of lithium absorption.

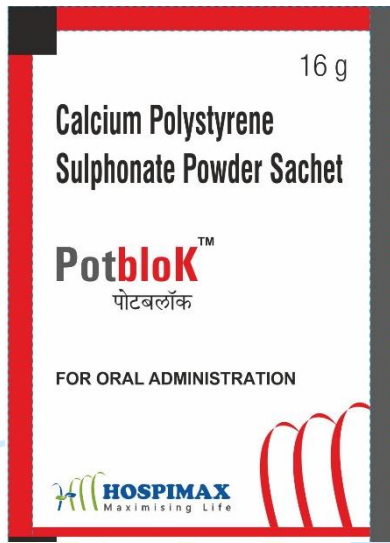
**Thyroxine:** Possible decrease of thyroxine absorption.

### **Adverse Reactions:**

Area of Affect	Adverse Effect
Gastrointestinal Disorders	Nausea, Vomiting, Abdominal pain,

	Constipation, Diarrhoea, Dyspepsia
Respiratory, Thoracic and Mediastinal Disorders	Bronchitis and/or bronchopneumonia
Metabolism and nutrition disorders:	Hypokalemia and hypercalcemia and their related clinical manifestations

**Pack Shot:**



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