normo-k™

Sodium Polystyrene Sulfonate USP

Potassium normalizing agent

Composition
Normo-K™: Each sachet contains Sodium Polystyrene Sulfonate USP 15 gm (Sodium content is approximately 100 mg per gm of the drug).

Pharmacology
Sodium Polystyrene Sulfonate is a cation exchange resin. It releases sodium ions in the stomach in exchange for hydrogen ions. When the resin reaches the large intestine the hydrogen ions are exchanged for free potassium ions; the resin is then eliminated in the feces. The net effect is lowering the amount of potassium available for absorption into the blood and increasing the amount that is excreted via the feces. The effect is a reduction of potassium levels in the body.

Indication
Indicated for the treatment of hyperkalemia.
(Hyperkalemia is mainly caused by Acute or Chronic Kidney Disease. Other causes may include Liver failure, Adrenal insufficiency, Use of certain drugs like ARB, ACE inhibitors, Beta blockers or Excessive use of Potassium supplements.)

Dosage and administration
Suspension of this drug should be freshly prepared and not to be stored beyond 24 hours.

Adults (including the elderly)
Oral Dose:
The average daily oral dose for adult is 15 gm to 60 gm (1 Sachet 1-4 times daily).

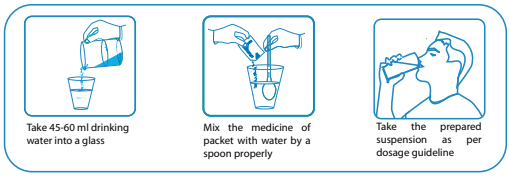
Rectal dose:
In patients who are unable to intake this medicine orally, rectal administration is possible (as enema). 30 gm to 50 gm of resin is given once or twice daily (at intervals of 6 hours). Each dose is administered as a warm emulsion (at body temperature) in 150 ml to 200 ml of aqueous vehicle (such as plain water, 10% dextrose in water or equal parts of water and 2% Methylcellulose suspension). The emulsion should be agitated gently during administration. The enema should be retained for as long as possible and should be followed by a cleansing enema.

Children
Oral dose:
In smaller children and infants correspondingly lower doses should be employed. An appropriate initial dose is 1 gm/kg body weight daily in divided doses in acute hyperkalemia. For maintenance therapy, dosage may be reduced to 0.5 gm/kg body weight daily.

Rectal dose:
When refused by mouth, the resin may be given rectally using a dose at least as much as that which would have been given orally. The resin should be suspended in a proportional amount of 10% Dextrose in water. Following retention of the enema, the colon should be irrigated to ensure adequate removal of the resin.

Neonates
Rectal dose:
Since it is advised that the oral route should not be employed, only rectal administration should be considered. With rectal administration, the minimum effective dosage within the range of 0.5 to 1 gm/kg of resin should be employed. The resultant suspension should be diluted as for adults. Following administration of the resin, the colon should be adequately irrigated to ensure recovery of the resin.

Mixing procedure
Each dose should be given as a suspension in a small quantity of water or, for greater palatability, in sweetened liquid or syrup (but not with orange or other fruit juices which contain potassium). The amount of fluid usually ranges from 20 ml to 100 ml, depending on the dose. It may be simply determined by allowing 3 ml to 4 ml per gram of drug. The prepared suspension should be administered by placing and maintaining the patient in an upright position. The resin may be introduced into the stomach through a plastic tube. If desired, it may be mixed with a diet appropriate for a patient in renal failure.The intensity and duration of therapy depend upon the severity and resistance of hyperkalemia. **Normo-K**™ should not be heated because it may alter the exchange properties of the resin.



Contraindication
Sodium Polystyrene Sulfonate is contraindicated in the following conditions: patients with hypokalemia, patients with a history of hypersensitivity to polystyrene sulfonate resins, obstructive bowel disease, neonates with reduced gut motility (postoperatively or drug induced) and oral administration in neonates.

Precaution
Caution is advised when this product is administered to patients who cannot tolerate even a small increase in sodium loads (i.e., severe congestive heart failure, severe hypertension, or marked edema). In such instances compensatory restriction of sodium intake from other sources may be indicated.
In the event of clinically significant constipation, treatment with this drug should be discontinued until normal bowel motion is resumed. Magnesium-containing laxatives or sorbitol should not be used.

Adverse reaction
The drug may cause some degree of gastric irritation. Anorexia, nausea, vomiting, and constipation may occur especially if high doses are given. Also, hypokalemia, hypocalcemia, and significant sodium retention, and their related clinical manifestations, may occur. Occasionally diarrhea develops. Large doses in elderly individuals may cause fecal impaction. Rare instances of colonic necrosis have been reported. Intestinal obstruction due to concretions of aluminum hydroxide, when used in combination with such resin has been reported.

Drug Interaction
Sodium Polystyrene Sulfonate may cause drug interactions with Antacids, Non-absorbable cation-donating antacids and laxatives, Digitalis, Sorbitol, Lithium, Thyroxine.

Use in Pregnancy & Lactation
Pregnancy Category C. Animal reproduction studies have not been conducted with Sodium Polystyrene Sulfonate. It is also not known whether it can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

Use in Children
The effectiveness in pediatric patients has not been established. In neonates, it should not be given by the oral route. Due to the risk of digestive hemorrhage or colonic necrosis, particular care should be observed in premature infants or low birth weight infants.

Overdosage
Overdosage may result in electrolyte disturbances including hypokalemia, hypocalcemia, and hypomagnesemia. Biochemical disturbances resulting from overdosage may give rise to clinical signs and symptoms of hypokalemia, including: irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia, which may progress to frank paralysis and/or apnea.

Storage Condition
Store below 300C. Keep out of the reach of children. Suspension of this drug should be freshly prepared and not to be stored beyond 24 hours.

How supplied
Normo-K™: Each box contains 10 Sachets of **Normo-K**™. Each Alu-Alu sachet contains Sodium Polystyrene Sulfonate USP 15 gm.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH