INFORMATION FOR THE CONSUMER

JAMP Sodium Polystyrene Sulfonate
Powder for Suspension, 1 g / g

DESCRIPTION OF THE PRODUCT

JAMP Sodium Polystyrene Sulfonate (sodium polystyrene sulfonate) is a golden brown, odorless fine powder with a characteristic taste of sodium polystyrene sulfonate. JAMP Sodium Polystyrene Sulfonate is a cation-exchange resin prepared in the sodium phase, with an in vivo exchange capacity of approximately 1 mmol (in vitro approximately 3.1 mmol) of potassium per gram. The sodium content is approximately 4.1 mmol (94.3 mg) per gram of the drug. JAMP Sodium Polystyrene Sulfonate can be administered either orally or as an enema.

What the medicinal ingredient is:
Sodium polystyrene sulfonate

What the non-medicinal ingredients are:
None

What dosage forms it comes in:
Powder for suspension

What it does:
Sodium polystyrene sulfonate is not absorbed from the gastrointestinal tract. As the resin passes through the gastrointestinal tract, the resin removes the potassium ions by exchanging it for sodium ions. Most of this action occurs in the large intestine, which excretes potassium ions to a greater degree than does the small intestine. Potassium exchange also occurs in the colon following retention of the resin, when administered as an enema. The efficiency of this process is limited and unpredictable. It commonly approximates the order of 33 per cent but the range is so large that definite indices of electrolyte balance must be clearly monitored. Metabolic data are unavailable.

INDICATION

JAMP Sodium Polystyrene Sulfonate is indicated for the treatment of hyperkalemia.

CONTRAINDICATIONS

JAMP Sodium Polystyrene Sulfonate should not be administered to patients with the following conditions:
- serum potassium <5 mmol / L
- history of hypersensitivity to polystyrene sulfonate resins
- obstructive bowel disease

JAMP Sodium Polystyrene Sulfonate should not be administered ***orally*** to neonates or in neonates with reduced gut motility (postoperatively or drug induced).

POSSIBLE SIDE EFFECTS

Side effects may include:
- Nausea and vomiting
- Diarrhea
- Loss of appetite

If any of these affects you severely, tell your doctor, nurse or pharmacist.
- **Constipation** (bloating and swelling of the abdomen)
- **Abdominal pain** (pain in your stomach and rectum)
- **Stomach irritation and bleeding** (vomit that looks like coffee grounds)
- **Rectal bleeding** (black bloody or tarry stools)
- **Allergic reaction** (rash; itching; swelling of the face, tongue and throat; severe dizziness and trouble breathing)
- **High level of sodium** (swelling)
- **Low level of potassium** (muscle cramps, feeling tired, confused, having muscle weakness or change in the heart rate)
- **Low level of calcium** (feeling nervous or unable to relax, having fits, or muscle cramps)
- **Fecal Impaction** (leaking liquid stool, stomach pain, feeling the need to push, nausea, vomiting, loss of appetite)
- **Bowel obstruction** (cramping, severe stomach pain, vomiting, bloating, constipation, inability to pass gas)
- **Bowel perforation** (severe stomach pain, chills, fever, nausea vomiting)

This is not a complete list of side effects. For any unexpected effects while taking JAMP Sodium Polystyrene Sulfonate, contact your doctor or pharmacist.

WARNINGS AND PRECAUTIONS

BEFORE you use JAMP Sodium Polystyrene Sulfonate, talk to your doctor, nurse or pharmacist if you have or have had any medical conditions, especially the following:
- Heart problems
- High blood pressure
- Problems with your bowel or constipation
- Severe burns
- Low blood volume, which can occur with dehydration or bleeding
- Electrolyte imbalance. JAMP Sodium Polystyrene Sulfonate therapy can worsen these imbalances. Your doctor may want to check the levels of the electrolytes in your blood more frequently during treatment.
- Kidney problems
- Edema (swelling of the face, hands or feet with fluid)
- You require low salt diet.
- You are pregnant or intend to become pregnant.
- You are breastfeeding. It is not known if JAMP Sodium Polystyrene Sulfonate passes into breast milk.

When taken by mouth, avoid taking JAMP Sodium Polystyrene Sulfonate at the same time as other orally administered medications (see “PROPER USE OF THIS MEDICATION”).

Magnesium containing laxatives should not be used with JAMP Sodium Polystyrene Sulfonate.

DRUG INTERACTIONS

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements or alternative medicines (non-prescription drugs or over the counter drugs).

When taken by mouth, JAMP Sodium Polystyrene Sulfonate may interfere with how other oral medicines are absorbed (see “PROPER USE OF THIS MEDICATION”).

The following may interact with JAMP Sodium Polystyrene Sulfonate:
- Digoxin, a medicine used for heart problems.
- Laxatives such as magnesium hydroxide or aluminium carbonate
- Thyroxine, a medicine for hypothyroidism
- Lithium, a medicine which can be used to treat bipolar disorder.
- Antacids containing aluminium or magnesium
- Sorbitol (a ‘sugar free’ sweetener used to sweeten food).
- Immunosuppressant drugs

PROPER USE OF THIS MEDICATION

USUAL DOSE:
JAMP Sodium Polystyrene Sulfonate can be given by mouth or in the rectum.

The amount of JAMP Sodium Polystyrene Sulfonate you need to take will depend upon the amount of potassium in your blood.

Once the mixture has been prepared, it should be used straight away. If it needs to be stored, it should be stored for no longer than 24 hours. Do not heat JAMP Sodium Polystyrene Sulfonate.

Your doctor will decide exactly how much JAMP Sodium Polystyrene Sulfonate you need to take. The usual doses are:

ORAL DOSING

When taken by mouth, JAMP Sodium Polystyrene Sulfonate should be taken at least 3 hours before or 3 hours after other oral medications.
For patients with gastroparesis (a condition preventing your stomach from emptying properly), a 6-hour separation should be considered.
Consult your health care provider for recommendations (see "WARNINGS AND PRECAUTIONS" and DRUG INTERACTIONS).

JAMP Sodium Polystyrene Sulfonate powder is usually given by mouth mixed in a small amount of water. It can also be mixed with sweetened liquid. Do NOT mix JAMP Sodium Polystyrene Sulfonate with orange juice or fruit juice which contains potassium.

JAMP Sodium Polystyrene Sulfonate is a powder. Be careful not to inhale it accidentally. Breathing in the powder may cause coughing and shortness of breath.

Your doctor will regularly check the potassium, calcium and magnesium levels in your blood. The doctor may change the dose or stop the JAMP Sodium Polystyrene Sulfonate depending on what the results of these blood tests are.

Adults, including the elderly:
15 g one to four times daily as indicated above.

Children:
You should follow the dosing recommended by your doctor. For children, JAMP Sodium Polystyrene Sulfonate is preferably given with water (NOT a fruit juice because of the high potassium content) or a little jam or honey.

Newborn babies (neonates)
JAMP Sodium Polystyrene Sulfonate should not be given by mouth.

RECTAL DOSING
The enema is usually given by a doctor or nurse.

Adults:
The enema should be prepared by the pharmacist or the nurse. 30 to 45g should be administered once or twice daily at interval of six hours. The enema should be retained in the rectum for as long as possible. Afterwards, the colon needs to be washed out to remove JAMP Sodium Polystyrene Sulfonate.

Children and infants:
The enema should be prepared by the pharmacist or the nurse. The enema should be retained in the rectum for as long as possible. Afterwards, the colon needs to be washed out to remove JAMP Sodium Polystyrene Sulfonate.

OVERDOSE:
Biochemical disturbances resulting from overdosage may give rise to clinical signs and symptoms of hypokalemia, including irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia, and eventually frank paralysis. Apnea may be a serious consequence of the progression. Electrocardiographic changes may be consistent with hypokalemia; cardiac arrhythmia may occur. Hypocalcemic tetany may occur.

Appropriate measures should be taken to correct serum electrolytes (potassium, calcium). The resin should be removed from the alimentary tract by appropriate use of laxatives or enemas.

MISSED DOSE:
Do not take a double dose to make up for the dose you have missed. If it is almost time for the dose, skip the dose you missed and take the next dose when you are meant to.

PACKING/ PACK SIZES

In white opaque HDPE jars of 454 g with white opaque polypropylene CT closure with liner.

HOW TO STORE IT

Store powder below 30°C.
Keep out of reach and sight of children.

MORE INFORMATION

If you want more information about JAMP Sodium Polystyrene Sulfonate:
• Talk to your healthcare professional

Product Owner
JAMP Pharma Corporation,
1310 rue Nobel, Boucherville, Quebec, J4B 5H3, Canada

Manufacturer
Sava Healthcare Ltd.
GIDC Estate, 507-B-512,
Wadhwan City - 363 035,
Surendranagar, India

Registration No. :

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For Healthcare Professional Use As Enema:

The resin may also be given, although with less effective results, in a daily enema (for adults) consisting of 30 to 45 g once or twice daily at 6 hour intervals. Each dose is administered as a warm emulsion (at body temperature) in 150 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 followed by a cleansing enema. Use of sorbitol in enemas in contraindicated. After the initial cleansing enema, a soft, large size (French 28) rubber tube is inserted into the rectum for a distance of about 20 cm, with the tip well into the sigmoid colon, and taped in place. The resin is then suspended in the appropriate amount of water or 10% dextrose at body temperature and introduced by gravity, while the particles are kept in suspension by stirring.

The suspension is flushed with 50 or 100 mL of saline solution, following which the tube is clamped and left in place. If back leakage occurs, the hips are elevated on pillows or a knee-chest position is taken temporarily. A somewhat thicker suspension may be used, but care should be taken that no paste is formed, because the latter has a greatly reduced exchange surface and will be particularly ineffective, if deposited in the rectal ampulla. The suspension is kept in the sigmoid colon for several hours, if possible. Then, the colon is irrigated, with a nonsodium containing solution at body temperature in order to remove the resin. Two quarts of flushing solution may be necessary. The returns are drained constantly through a Y tube connection. The intensity and duration of therapy depends upon the severity and resistance of hyperkalemia.

The resin should not be heated as it may alter its exchange properties.