PRESCRIBING INFORMATION

PrSOLYSTAT®

Sodium Polystyrene Sulfonate Suspension, USP

Powder for Suspension: 1 g / g (For oral and rectal use)
Oral Suspension: 250 mg / mL (For oral use)

Cation Exchange Resin

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THERAPEUTIC CLASSIFICATION

Cation Exchange Resin

DESCRIPTION

SOLYSTAT Powder for Suspension
Each gram of light brown, finely ground powder contains 1 gram of sodium polystyrene sulfonate. The sodium content is approximately 4.1 mmol (94.3 mg) per gram of the drug. SOLYSTAT is a cation exchange resin prepared in the sodium phase. Exchange capacity: approximately 3 mmol of potassium per gram *in vitro* and approximately 1 mmol of potassium per gram *in vivo*. SOLYSTAT can be administered either orally or as an enema.

SOLYSTAT Oral Suspension
Each 60 mL of brown, cherry-flavored suspension contains 15 g of sodium polystyrene sulfonate USP and 14.1 g of sorbitol. Also contains methylparaben and propylparaben as preservatives. The sodium content is 65 mmol (1.5 g)/60 mL. Exchange capacity: approximately 3 mmol of potassium per 4 mL (per gram of resin) of suspension *in vitro* and approximately 1 mmol *in vivo*.

ACTION

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 them 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

SOLYSTAT (sodium polystyrene sulfonate suspension) is indicated for the treatment of hyperkalemia.

CONTRAINDICATIONS

SOLYSTAT (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

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

WARNINGS AND PRECAUTIONS

Alternative therapy in severe hyperkalemia: Since effective lowering of serum potassium with SOLYSTAT may take hours to days, treatment with this drug alone may be insufficient to rapidly correct severe hyperkalemia associated with states of rapid tissue breakdown (e.g. burns and renal failure). In such instances, some form of dialysis (peritoneal or hemo-) may be imperative.

If hyperkalemia is so marked as to constitute a medical emergency (e.g. serum potassium above 7.5 mmol/liter), immediate treatment with intravenous glucose and insulin, or intravenous sodium bicarbonate may be necessary as a temporary measure to lower serum potassium, while other long-term potassium lowering therapy is initiated.

Binding to other orally administered medications: When administered orally, SOLYSTAT may bind to other orally administered medications, which could decrease their gastrointestinal absorption and efficacy. Avoid co-administration of SOLYSTAT with other orally administered medications. Administer SOLYSTAT at least 3 hours before or 3 hours after administration of other oral medications. For patients with gastroparesis, a 6-hour separation should be considered (see **DRUG INTERACTIONS** and **DOSAGE AND ADMINISTRATION, Powder for Suspension**).

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 sodium polystyrene sulfonate 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 (see **DRUG INTERACTIONS** and **ADVERSE REACTIONS**).

Hypokalemia: SOLYSTAT therapy can precipitate serious potassium deficiency and the possibility of severe potassium depletion should be considered. It is therefore imperative to

determine serum potassium levels at least daily and more frequently when indicated. Adequate clinical and biochemical control is essential during treatment especially in patients on digitalis. Therapy should be discontinued as soon as serum potassium falls below 5 mmol/L (see **DRUG INTERACTIONS**). Since intracellular potassium deficiency is not always reflected by serum potassium levels, the level at which treatment with SOLYSTAT should be discontinued must be determined individually for each patient. The patient's clinical condition and electrocardiogram are important in making this determination.

Early clinical signs of severe hypokalemia include a pattern of irritability, confusion and delayed thought processes. Severe hypokalemia is often associated with a lengthened Q-T interval, widening, flattening or inversion of the T wave, and the appearance of U waves on the electrocardiogram (ECG). Cardiac arrhythmias such as premature atrial, nodal and ventricular contractions, and supraventricular and ventricular tachycardias may also occur. Marked hypokalemia can also be manifested by severe muscle weakness, at times extending into frank paralysis. The toxic effects of digitalis on the heart, especially various ventricular arrhythmia and A-V nodal dissociation, are likely to be exaggerated by hypokalemia. These effects can occur even though serum digoxin concentration is within the 'normal range'.

Other electrolytes disturbances: Like all cation-exchange resins, sodium polystyrene sulfonate is not totally selective (for potassium) in its actions, and small amounts of other cations such as magnesium and calcium can also be lost during treatment. Patients receiving SOLYSTAT should be monitored for all applicable electrolyte disturbances.

Other risks: In the event of clinically significant constipation, treatment with the resin should be discontinued until normal bowel motion is resumed. Magnesium-containing laxatives should not be used (see **DRUG INTERACTIONS**).

The patient should be positioned carefully when ingesting the resin, in order to avoid aspiration, which could lead to bronchopulmonary complications.

Special Populations

Children and neonates: In neonates, SOLYSTAT should not be given by the ***oral*** route. In both children and neonates, particular care should be observed with rectal administration. Excessive dosage or inadequate dilution could result in impaction of the resin.

Due to the risk of gastrointestinal tract hemorrhage, colonic necrosis, or sodium overload, particular care should be observed in premature infants or low birth weight infants.

Patients at risk from an increase in sodium load: During the resin's action in the intestinal tract, sodium is released mole for mole with potassium uptake. A single dose of sodium polystyrene sulfonate (15 grams) contains approximately 60 mmol of sodium. Since the resin is a source of sodium, caution is advised when SOLYSTAT is administered to patients who cannot tolerate even a small increase in sodium loads and for whom an increase in sodium load may be detrimental (i.e. severe congestive heart failure, severe hypertension, marked edema or renal damage). In such instances, compensatory restriction of sodium intake from other sources may

be indicated and adequate clinical and biochemical control is essential. The calcium form of the resin may offer advantages in this situation.

Other electrolyte disturbances: Like all cation-exchange resins, sodium polystyrene sulfonate is not totally selective (for potassium) in its actions, and small amounts of other cations such as magnesium and calcium can also be lost during treatment. Patients receiving SOLYSTAT should be monitored for all applicable electrolyte disturbances.

Other risks: In the event of clinically significant constipation, treatment with the resin should be discontinued until normal bowel motion is resumed. Magnesium-containing laxatives should not be used (see **DRUG INTERACTIONS**).

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Children and neonates: In neonates, SOLYSTAT should not be given by the ***oral*** route. In both children and neonates, particular care should be observed with rectal administration. Excessive dosage or inadequate dilution could result in impaction of the resin.

Due to the risk of gastrointestinal tract hemorrhage, colonic necrosis, or sodium overload, particular care should be observed in premature infants or low birth weight infants.

DRUG INTERACTIONS

Orally administered medications: When administered orally, SOLYSTAT has the potential to bind to other orally administered medications. Binding of SOLYSTAT to other oral medications could decrease their gastrointestinal absorption and efficacy. Dosing separation of SOLYSTAT from other orally administered medications is recommended (see **DOSAGE AND ADMINISTRATION** and **WARNINGS AND PRECAUTIONS**).

Sorbitol (oral or rectal): Concomitant administration of sorbitol with SOLYSTAT is not recommended due to cases of intestinal necrosis, and other serious gastrointestinal adverse reactions, which may be fatal (see **WARNINGS AND PRECAUTIONS** and **ADVERSE REACTIONS**).

To be used with caution:

Cation donating agents: may reduce the effectiveness of the resin in binding potassium.

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

Digitalis drugs: the toxic effects of digitalis on the heart, especially various ventricular arrhythmias and A-V nodal dissociation, are likely to be exaggerated if hypokalemia is allowed to develop (see **WARNINGS AND PRECAUTIONS**).

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.

Lithium: possible decrease of lithium absorption.

Thyroxine: possible decrease of thyroxine absorption.

PREGNANCY

Sodium polystyrene sulfonate is not absorbed from the gastrointestinal tract. No data are available concerning the use of polystyrene sulfonate resins in humans during pregnancy.

LACTATION

Sodium polystyrene sulfonate is not absorbed from the gastrointestinal tract. No data are available concerning the use of polystyrene sulfonate resins in humans during lactation.

OVERDOSAGE

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.

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

ADVERSE REACTIONS

Gastrointestinal disorders

SOLYSTAT (sodium polystyrene sulfonate) may cause some degree of gastric irritation. Anorexia, nausea, vomiting and constipation may occur especially if high doses are given. Occasionally diarrhea develops.

Large doses in elderly individuals may cause fecal impaction. These effects may be obviated through usage of the resin in enemas as described under **DOSAGE AND ADMINISTRATION**.

Fecal impaction following rectal administration particularly in children and gastrointestinal concretions (bezoars) following oral administration have been reported. Gastrointestinal stenosis and intestinal obstruction have also been reported, possibly due to co-existing pathology or inadequate dilution of the resin. Intestinal obstruction due to concretions of aluminum hydroxide has been reported when aluminum hydroxide was used in combination with sodium polystyrene sulfonate.

Gastrointestinal ischemia, ischemic colitis, rectal haemorrhage, gastrointestinal tract ulceration or necrosis which could lead to intestinal perforation have been reported, which is sometimes fatal.

The majority of cases have been reported with concomitant use of sorbitol (see **WARNINGS AND PRECAUTIONS** and **DRUG INTERACTIONS**).

Metabolism and nutrition disorders
In accordance with its pharmacological actions, the resin may give rise to sodium retention, hypokalemia and hypocalcemia, and their related clinical manifestations (see **WARNINGS AND PRECAUTIONS** and **OVERDOSAGE**). Cases of hypomagnesemia have been reported.

Respiratory, thoracic and mediastinal disorders
Some cases of acute bronchitis and/or bronchopneumonia associated with inhalation of particles of sodium polystyrene sulfonate have been described.

DOSAGE AND ADMINISTRATION

SOLYSTAT (sodium polystyrene sulfonate) is for oral or rectal administration only. The dosage recommendations given below are approximate. The precise requirements for each individual patient should be determined on the basis of regular clinical and biochemical assessments.

Powder for Suspension

Suspensions of SOLYSTAT should be freshly prepared and not stored beyond 24 hours.

SOLYSTAT powder should not be heated as heating may alter the exchange properties of the resin.

Adults, Including the Elderly

Oral: The average daily adult dose of the resin is 15 to 60 grams. This is provided by administering 15 grams (approximately 4 level teaspoons) of SOLYSTAT one to four times daily. One gram of SOLYSTAT powder contains 4.1 mmol of sodium; one level teaspoon contains approximately 3.5 grams of SOLYSTAT powder and 15 mmol of sodium. A heaping teaspoon may contain as much as 10-12 grams of SOLYSTAT powder. Since the *in vivo* efficiency of sodium-potassium exchange resins is approximately 33 per cent, about one third of the resin's actual sodium content is being delivered to the body.

Each dose should be given as a suspension in a small quantity of water or, for greater palatability, in syrup, but not in orange juice or other fruit juices that are known to contain potassium. The amount of fluid usually ranges from 20 to 100 mL, depending on the dose. It may be simply determined by allowing 3 to 4 mL per gram of resin.

Administer SOLYSTAT at least 3 hours before or 3 hours after other oral medications. For patients with gastroparesis, a 6-hour separation should be considered (see **WARNINGS AND PRECAUTIONS** and **DRUG INTERACTIONS**).

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.

Rectal: For adults, the resin may also be given, although with less effective results, in a daily enema. Thirty (30) to 50 g of resin is given once or twice daily (at intervals of six hours). Each dose is administered as a warm emulsion (at body temperature) in 150 to 200 mL of aqueous vehicle (such as plain water, 10 per cent dextrose in water or equal parts of water and 2 per cent 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.

After the initial cleansing enema, insert a soft, large size (French 28) rubber tube into the rectum for a distance of about 20 cm, with the tip well into the sigmoid colon. Then tape the tube in place. Suspend the resin in the appropriate amount of water or 10 percent dextrose in water at body temperature. While constantly stirring to keep the particles in suspension, introduce the suspension into the colon by gravitational flow. The suspension should be 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 may be elevated on pillows or a temporary knee-chest position may be taken. A somewhat thicker suspension may be used, but care should be taken that no paste is formed. Paste formation has a greatly reduced exchange surface and is particularly ineffective, if deposited in the rectal ampulla. If possible, keep the suspension in the sigmoid colon for several hours. In order to remove the resin, irrigate the colon with non-sodium containing solution at body temperature. Two quarts of flushing solution may be necessary. The returns should be drained constantly through a Y tube connection. While the use of sorbitol is not recommended, particular attention should be paid to the cleansing enema whenever sorbitol has been used.

It should be noted that the rectal route of administration should be reserved for patients who are vomiting or who have upper gastrointestinal tract problems, including paralytic ileus. The rectal route may also be used simultaneously with oral administration in cases where more rapid initial results are desirable. If both routes are used initially, it is probably unnecessary to continue rectal administration once the oral resin has reached the rectum.

The intensity and duration of therapy depends upon the severity and resistance of hyperkalemia.

Children

Oral: In smaller children and infants, correspondingly lower doses should be employed. Calculation of the dose may be based upon the exchange rate of 1 mmol of potassium per gram

of resin. An appropriate initial dose is 1 g/kg body weight daily in divided doses in acute hyperkalemia. For maintenance therapy, dosage may be reduced to 0.5 g/kg body weight daily.

Rectal: When refused by mouth, the resin may be given rectally using a dose at least as great 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 (see **WARNINGS AND PRECAUTIONS**).

Neonates

Rectal: 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 g/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 (see **WARNINGS AND PRECAUTIONS**).

Oral Suspension

Adults, Including the Elderly

Oral Only: Each dose should be given as a suspension in a small quantity of water or, for greater palatability, in syrup, but not in orange juice or other fruit juices that are known to contain potassium. The amount of fluid usually ranges from 20 to 100 mL, depending on the dose. It may be simply determined by allowing 3 to 4 mL per gram of resin.

The average daily adult dose of the resin is 15 to 60 grams (60 to 240 mL). This is provided by administering 60 mL (15 grams) of SOLYSTAT one to four times daily. Since the *in vivo* efficiency of sodium-potassium exchange resins is approximately 33 per cent, about one third of the resin's actual sodium content is being delivered to the body.

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 depends upon the severity and resistance of hyperkalemia.

Children

Oral Only: In smaller children and infants, correspondingly lower doses should be employed. Calculation of the dose may be based upon the exchange rate of 1 mmol of potassium per g of resin. An appropriate initial dose is 1 g/kg (4 mL/kg) body weight daily in divided doses in acute hyperkalemia. For maintenance therapy, dosage may be reduced to 0.5 g/kg body weight daily.

AVAILABILITY

Powder for Suspension
Supplied in jars of 454 g.

Oral Suspension
Supplied in unit dose plastic bottles of 60 mL and in plastic bottles of 500 mL.

STORAGE

Powder for Suspension
Store between 15°C and 30°C (59°F and 86°F). Store in a well-closed container.

Oral Suspension
Store between 15°C and 30°C (59°F and 86°F). Store in a well-closed container. Protect from freezing and from excessive heat.

REFERENCES

1. KAYEXALATE® (Sodium Polystyrene Sulfonate) Prescribing Information, Sanofi-Aventis Canada Inc., Control #: 217331, Date of Revision: September 19, 2018.

IMPORTANT: PLEASE READ

CONSUMER INFORMATION

PrSOLYSTAT
(Sodium Polystyrene Sulfonate Suspension)

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SOLYSTAT. Contact your doctor, nurse or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
SOLYSTAT is used to remove high amounts of potassium from the blood.

What it does:
SOLYSTAT attaches to the extra potassium in the body, particularly in the large intestine, so it can be removed from the body in the stool.

When it should not be used:
Do not take SOLYSTAT if:
- You have a bowel obstruction (blocked intestine).
- You have low levels of potassium in your blood.
- If you are allergic to sodium polystyrene sulfonate

Do not use SOLYSTAT in newborn babies who have slowed movements in their gut (caused by other medications or following surgery).

Do not give SOLYSTAT by mouth to newborn babies. SOLYSTAT should only be given rectally to newborns.

What the medicinal ingredient is:
Sodium polystyrene sulfonate

What the non-medicinal ingredients are:
Powder for suspension: None
Oral suspension: Sorbitol, methylparaben, propylparaben

What dosage forms it comes in:
- Powder for suspension (for oral or rectal use)
- Oral suspension (for oral use)

WARNINGS AND PRECAUTIONS

BEFORE you use SOLYSTAT, 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. SOLYSTAT 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 SOLYSTAT passes into breast milk.

When taken by mouth, avoid taking SOLYSTAT at the same time as other orally administered medications (see "PROPER USE OF THIS MEDICATION").

Magnesium containing laxatives should not be used with SOLYSTAT.

INTERACTIONS WITH THIS MEDICATION

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, SOLYSTAT may interfere with how other oral medicines are absorbed (see "PROPER USE OF THIS MEDICATION").

The following may interact with SOLYSTAT:
- Digoxin, a medicine used for heart problems.
- Laxatives such as magnesium hydroxide or aluminum carbonate
- Thyroxine, a medicine for hypothyroidism
- Lithium, a medicine which can be used to treat bipolar disorder.
- Antacids containing aluminum or magnesium
- Sorbitol (a 'sugar free' sweetener used to sweeten food).

- Immunosuppressant drugs

PROPER USE OF THIS MEDICATION

Usual dose:
SOLYSTAT *Powder for Suspension* can be given by mouth or in the rectum.
SOLYSTAT *Oral Suspension* is given only by mouth.

The amount of SOLYSTAT you need to take will depend upon the amount of potassium in your blood.

Once the mixture of SOLYSTAT *Powder for Suspension* 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 SOLYSTAT.

Your doctor will decide exactly how much SOLYSTAT you need to take. The usual doses are:

ORAL DOSING

When taken by mouth, SOLYSTAT 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 "INTERACTIONS WITH THIS MEDICATION").

- SOLYSTAT *Powder for Suspension* is usually given by mouth mixed in a small amount of water. It can also be mixed with food or sweetened liquid. Do NOT mix SOLYSTAT with orange juice or fruit juice which contains potassium.
- SOLYSTAT *Oral Suspension* does not require any preparation before use. Shake the bottle well before drinking.

Be careful not to inhale SOLYSTAT *Powder for Suspension* 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 SOLYSTAT depending on what the results of these blood tests are.

Adults, including the elderly:

- SOLYSTAT *Powder for Suspension*: 15 grams (about 4 level teaspoons) one to four times daily as indicated above.
- SOLYSTAT *Oral Suspension*: 15 grams (60 mL) one to four times daily as indicated above.

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

Newborn babies (neonates)
SOLYSTAT should not be given by mouth.

RECTAL DOSING

Rectal dosing only applies to SOLYSTAT *Powder for Suspension*. The enema is usually given by a doctor or nurse.

Adults:
The enema should be prepared by the pharmacist or the nurse. The dosage 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 SOLYSTAT.

Children and newborn babies (neonates):
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 SOLYSTAT.

Overdose:
Taking too much SOLYSTAT may reduce your potassium in your blood below the normal level. If you take too much of this medication, you may feel irritable, confused, have muscle weakness, have diminished reflexes or paralysis.

If you think you have taken too much SOLYSTAT, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Nausea and vomiting
- Diarrhea
- Loss of appetite

If any of these affects you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Constipation (bloating and swelling of the abdomen)			**x**
Abdominal pain (pain in your stomach and rectum)			**x**
Stomach irritation and bleeding (vomit that looks like coffee grounds)			**x**
Rectal bleeding (black bloody or tarry stools)			**x**
Allergic reaction (rash; itching; swelling of the face, tongue and throat; severe dizziness and trouble breathing)			**x**
High level of sodium (swelling)		**x**	
Low level of potassium (muscle cramps, feeling tired, confused, having muscle weakness or change in the heart rate)		**x**	
Low level of calcium (feeling nervous or unable to relax, having fits, or muscle cramps)			
cal Impaction aking liquid stool, stomach pain, feeling the need to push, nausea, vomiting, loss of appetite)			**x**
Bowel obstruction (cramping, severe stomach pain, vomiting, bloating, constipation, inability to pass gas)			**x**
Bowel perforation (severe stomach pain, chills, fever, nausea vomiting)			**x**

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

HOW TO STORE IT

Store at room temperature (15°C to 30°C).
Keep out of reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about SOLYSTAT:

- Talk to your healthcare professional
- Find the full Prescribing Information that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada

website (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp); the manufacturer's website (www.pendopharm.com); or by calling 1-888-550-6060.

This leaflet was prepared by PENDOPHARM, Division of Pharmascience Inc.

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