

IMPORTANT: PLEASE READ

CONSUMER INFORMATION

PrKAYEXALATE®
(sodium polystyrene sulfonate powder)

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

ABOUT THIS MEDICATION

What the medication is used for:

KAYEXALATE is used to remove high amounts of potassium from the blood.

What it does:

KAYEXALATE 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 KAYELAXATE 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 KAYEXALATE in newborn babies who have slowed movements in their gut (caused by other medications or following surgery).

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

What the medicinal ingredient is:

Sodium polystyrene sulfonate

What the non-medicinal ingredients are:

None

What dosage forms it comes in:

Powder

WARNINGS AND PRECAUTIONS

BEFORE you use KAYEXALATE, 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 movements such as delayed bowel movements or constipation
- Severe burns
- Low blood volume, which can occur with dehydration or bleeding
- Have been told you have an electrolyte imbalance. KAYEXALATE therapy can worsen these imbalances. Your doctor may want to check the levels of the electrolytes in your blood more frequently during treatment.
- Are undergoing dialysis or have any kidney problems
- Edema (swelling of the face, hands or feet with fluid)
- You require low salt diet.
- You are pregnant, think you are pregnant, or intend to become pregnant.
- You are breastfeeding. It is not known if KAYEXALATE passes into breast milk.
- You are taking a sweetener called sorbitol (a «sugar-free» sweetener used to sweeten food).
- You have problems with your bowel, bowel movements or delayed bowel movements (constipation) caused by drugs or following a surgery.

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

Magnesium containing laxatives should not be used with KAYEXALATE.

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

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medicines (non-prescription drugs or over the counter drugs).

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

The following may interact with KAYEXALATE:

- 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
- Drugs that slow the stomach from emptying (drugs such as anticholinergics or narcotics)

PROPER USE OF THIS MEDICATION

Usual dose:

KAYEXALATE can be given by mouth or in the rectum.

The amount of KAYEXALATE 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 KAYEXALATE.

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

ORAL DOSING

When taken by mouth, KAYEXALATE 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”).

KAYEXALATE powder 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 KEYEXALATE with orange juice or fruit juice which contains potassium.

KAYEXALATE 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 KAYEXALATE 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, KEYAXALATE 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)

KAYEXALATE 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. 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 KAYEXALATE.

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 KAYEXALATE.

Overdose:

Taking too much KAYEXALATE 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.

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In case of drug overdose, contact a health care practitioner, 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

These are not all the possible side effects you may have when taking KAYEXALATE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Nausea and vomiting
- Diarrhea
- Loss of appetite

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN FREQUENCY			
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: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			x
Hypernatremia (high level of sodium: swelling		x	

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	Only if severe	In all cases			Only if severe	In all cases	
Hypokalemia (low level of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, feeling of skipped heart beats or palpitations, fatigue, tingling or numbness		x		Gastrointestinal Ischemia / Ischemic Colitis (slow or no blood flow to the intestines): abdominal cramps, abdominal pain, bright red bowel movement, weight loss, diarrhea, nausea bloating.			x
Hypocalcemia (low level of calcium): feeling nervous or unable to relax, having fits, or muscle cramps.		x		Peritonitis (swelling of the lining of the belly or stomach): abdominal pain or tenderness, bloating, fever, nausea and vomiting, loss of appetite, diarrhea, thirst, low urine, cannot pass stool or gas, fatigue, confusion.			x
Fecal impaction (blocked colon from a mass of stool) following rectal administration, particularly in children: abdominal pain, nausea and vomiting, liquid stool, urge to move bowels, loss of appetite, weight loss, malaise			x	Gastrointestinal Necrosis			
Bowel obstruction or gastrointestinal stenosis (the bowel or part of the gastrointestinal tract is partially or fully blocked): cramping, severe stomach pain, vomiting, bloating, constipation, inability to pass stool or gas, loss of appetite, swelling of the abdomen.			x	<i>This is not a complete list of side effects. For any unexpected effects while taking KAYEXALATE, contact your doctor or pharmacist.</i>			
Gastrointestinal necrosis and bowel perforation: severe stomach pain, chills, fever, nausea vomiting, bleeding from your rectum, swelling of the stomach, constipation, diarrhea, fever fainting, low uring and confusion.			x	<div style="background-color: black; color: white; text-align: center; padding: 5px; font-weight: bold;">HOW TO STORE IT</div> <p>Store at room temperature (15 to 30 °C).</p> <p>Keep out of reach and sight of children.</p>			

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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 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

This document plus the full product monograph, prepared for health professionals can be found at: www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927

This leaflet was prepared by sanofi-aventis Canada Inc.

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