PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Kayexalate Powder

Active ingredient and its quantity:
Sodium polystyrene sulfonate 99.934%
Inactive ingredients – see section 6.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
Keep this leaflet; you may need to read it again.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
If a side effect worsens or if you experience a side effect not mentioned in this leaflet, please refer to a doctor or pharmacist.
If you have further questions, refer to a doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is intended for the treatment of excess blood potassium (hyperkalaemia).
This preparation contains an ion-exchange resin which, when passing through the gastrointestinal tract, releases sodium ions and, in their place, binds mostly potassium ions. The preparation is not absorbed by the body.

Therapeutic group: Medicines for the treatment of hyperkalaemia and hyperphosphataemia.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient sodium polystyrene sulfonate or to any of the other components of this medicine (see details in section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- You have been told that you suffer from low blood potassium levels (hypokalemia).
- Your gut is partially or completely blocked (obstructive bowel disease).
- You are taking a sweetener called sorbitol ("no sugar" sweetener). This is because taking sorbitol and Kayexalate concomitantly may cause narrowing of the gut wall (gastrointestinal stenosis) and decreased blood flow to the gut wall (intestinal ischemia), which cause severe damage to the gut (necrosis and perforation). Do not take sorbitol during treatment with Kayexalate.
- Do not use in neonates with reduced gut motility (caused by surgery or medicinal treatment).
- Do not administer the medicine orally to neonates.

If one or more of the listed conditions apply to you, or if you are uncertain, talk to the doctor.

Special warnings regarding use of the medicine
Before treatment with this medicine, inform the doctor if:
You have or have suffered in the past from irregularities in the digestive system.
You have heart problems.
You have high blood pressure.
You have kidney problems.
You have swelling in your arms or legs (oedema).

Children
Exercise caution and consult the doctor before use in premature babies and in babies with a low birth weight or that have reduced intestinal motility.
Exercise caution to avoid overdose or inadequate dilution when administering to children and infants. Overdose may cause severe constipation.
If you are not sure if the listed conditions apply to you, consult the doctor before commencing treatment with Kayexalate.

Tests and follow-up
Blood tests
Your doctor will instruct you to regularly perform blood tests while you are taking this medicine. This is to check the levels of salts (potassium, sodium, calcium and magnesium) in your blood.

Drug interactions

If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, inform the doctor or pharmacist. This is because Kayexalate may affect the way certain medicines work, and certain medicines may affect the way Kayexalate works.
It is especially important to inform the doctor or pharmacist if you are taking:
- Medicines that contain salts such as magnesium, potassium or calcium. Consult your doctor if you are not sure.
- Some medicines for constipation (laxatives) that contain magnesium.
- Some medicines for indigestion (antacids) that contain magnesium or aluminum.
- Digoxin or medicines similar to digitalis - for heart problems.
- Levothyroxine or thyroxine – for treatment of an underactive thyroid.
- Lithium – for treatment of mental illnesses.

If you are uncertain if this applies to you, consult the doctor before commencing treatment with Kayexalate.

Pregnancy and breastfeeding
Consult the doctor before using this medicine if:
- You are pregnant, can become pregnant or think you may be pregnant.
- You are breastfeeding or plan to breastfeed.

Consult the doctor or pharmacist before use.

Important information about some of the ingredients in this medicine
Kayexalate contains 1400 to 1700 mg sodium (main component of cooking/table salt) in each 15 g dose. This is equivalent to 280-340% of the recommended maximum daily dietary intake of sodium for an adult.
Talk to your doctor or pharmacist if you need 15 g or more daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

- The dosage will depend on blood test results.
- For children, the dosage will be determined by the child's weight.
- Each Kayexalate measuring spoon contains 15 g of powder.
- It is forbidden to heat Kayexalate – heating can change the properties of the preparation.
- Consult the doctor with regard to prophylactic measures or treatment for constipation sometimes caused by use of the preparation.

Taking the medicine:

- This medicine is intended for oral or rectal use.
- Use the Kayexalate suspension immediately after preparing it.

Oral administration:

- Mix with a small amount of water up to half a cup, depending on the dose, and drink immediately. Sweetened water can be used to improve the taste. Similarly, a paste can be made with sweeteners, such as jam or honey.
- Do not mix this medicine with fruit juice; this may impair the activity of the medicine.
- Remain in an upright position when taking the medicine in order to prevent aspiration of the powder into the respiratory system.
- Take the medicine at least 3 hours before or 3 hours after other medicines you may take orally. If you are suffering from gastroparesis (a condition in which the stomach does not empty regularly), wait at least 6 hours before or after you take other medicines orally.

Rectal administration:

- A preparation for rectal use should be made. Refer to the medical staff for instructions.
  Try to keep the medicine in the rectum for at least 4-10 hours. Afterwards, wash the area thoroughly.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose!

If you accidentally took a higher dosage, or if a child accidentally swallowed the medicine, proceed to a hospital emergency room immediately and bring the package of the medicine with you.

If you took an overdose, you may suffer from the following signs:

- feeling irritable or confused
- being unable to concentrate
- muscle weakness and weakened reflexes that may lead to paralysis
- breathing problems
- faster or pounding heartbeat
- muscle cramps.

If you forgot to take this medicine at the scheduled time, do not take a double dose. Consult your doctor about when you should take your medicine.
Adhere to the treatment recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor or pharmacist.

If you stop taking the medicine: Take Kayexalate until your doctor tells you to stop the treatment. If you discontinue the treatment against the doctor's instructions, your ailment may recur.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Kayexalate may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Refer to a doctor immediately if you notice one or more of the following severe side effects:

- You have an allergic reaction. Signs may include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- Severe stomach pain, rectal pain.
- Bloating, severe constipation.
- Severe nausea and vomiting.
- Black, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds.
- Blood in vomit.

Refer to the doctor as soon as possible if you suffer from the following side effects:

- Feeling tired, confusion, muscle weakness, muscle cramps or a change in heart rate. These signs may be due to low levels of potassium in your body.
- Feeling jittery, having fits or muscle cramps. This may be due to low levels of calcium or magnesium in your body.
- High blood pressure, kidney problems, heart problems or swelling in the limbs. This may be due to high levels of sodium in your body.
- Stomach upset, pain in the gut, narrowing or blockage of the gut.
- Decreased blood flow to the gut wall which causes intense abdominal pain or collapse.
- Loss of appetite.
- Feeling sick, being sick, constipation or diarrhoea.
- Feeling short of breath or coughing. This may be the first sign of a serious chest infection, which can be caused by accidentally breathing in this medicine.

Side effects and drug interactions in children and infants:
Parents must inform the attending doctor of any side effects and about any other medicines being administered to the child!
See special warnings detailed above.

If a side effect occurs, if any of the side effects worsen, or persist for more than a few days, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. Do not discard any medicine in the wastewater or household waste. Ask your pharmacist how to dispose of medicines that you no longer use. These measures will help protect the environment.

Storage conditions:

Store at a temperature below 30°C. Close firmly to avoid penetration of light and humidity.

After opening for the first time, the preparation can be used for up to one month.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: saccharin, vanillin.
- What the medicine looks like and the contents of the package:
  Kayexalate is a brownish-yellow powder, packaged in a 454 g container with a 15 g measuring spoon.
- License Holder and Importer and its address: sanofi-aventis Israel ltd. Address: P.O.B 8090, Netanya.

Revised in September 2022 according to MOH guidelines.

This leaflet does not contain all the information about your medicine. If you have any question or are not sure about anything, please ask your doctor.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1415921158