

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in June 2016

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

The medicine is dispensed with a doctor's prescription only

SLOW-K® 600 mg

Sugar-coated prolonged-release tablets

Active ingredient:

Each tablet contains:
Potassium chloride 600 mg

Inactive ingredients:

See section 6 'Further information'. Also see 'Important information about some of the ingredients of the medicine' in section 2.

Read this leaflet carefully in its entirety before using the 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 for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

The medicine is not intended for children and infants. The safety and efficacy of the medicine have not been tested in children.

1. WHAT IS THE MEDICINE INTENDED FOR?

For prevention and treatment of low blood potassium levels (hypokalemia).

Slow-K contains potassium chloride in a special prolonged-release system that releases your medicine evenly throughout the day. Slow-K is used to treat or prevent low levels of potassium in your body. This condition might be caused as a result of: vomiting or diarrhea, if you are taking certain medicines, if you are suffering from certain kidney or gut problems, if you are suffering from certain metabolic diseases, if you do not receive enough potassium from your normal diet or if you are suffering from a genetic disease.

Slow-K is usually taken by patients who cannot take potassium chloride as a liquid or tablet that dissolves.

Therapeutic group: Potassium supplement.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- you are sensitive (allergic) to potassium chloride or any of the other ingredients of this medicine listed in section 6 "Further information"
- you have kidney failure
- you have severe or long-lasting diarrhea
- you have untreated Addison's disease (underactive adrenal glands)
- you have a hormonal problem called "hypo-aldosteronism"
- any part of your food pipe, stomach or gut has a narrowing in it
- you suffer from conditions such as: trauma, burns, muscle cramps and metabolic complications occurring after cancer treatment
- you have a blood problem called "metabolic acidosis"
- you have been told that your body has difficulty getting rid of potassium
- you have been told that you have high levels of potassium in your blood
- you have hyperkalemic periodic paralysis
- you are taking certain diuretics called "potassium sparing diuretics" such as spironolactone, triamterene, amiloride
- you have been told that you cannot tolerate or digest some sugars. Slow-K contains sucrose (a type of sugar)

Do not take this medicine if any of the above conditions apply to you. If you are not sure, talk to your doctor or pharmacist before taking Slow-K.

Special warnings regarding use of the medicine

⚠ Before treatment with Slow-K, tell the doctor if:

- you have had any surgery in or near your stomach or gut (such as colostomy, ileostomy or urostomy)
 - you have kidney, liver or heart problems
 - you suffer from stomach ulcers
 - you are pregnant or plan to get pregnant
 - you are breast-feeding
 - you have any problems with your digestive system like constipation, irritable bowel syndrome, bowel obstruction, cancer of the bowel, reflux, a condition in which "pockets" are formed in the bowel (diverticular disease), ulcers, hemorrhoids etc.
 - you suffer from a magnesium deficiency
- If any of the above conditions apply to you (or if you are not sure), consult the doctor or pharmacist before taking Slow-K.

⚠ Taking other medicines

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, because Slow-K can affect the way other medicines work. Also, other medicines can affect the way Slow-K works.

In particular, if you are taking:

- diuretics called "potassium sparing diuretics" such as spironolactone, triamterene or amiloride.
- Do not take Slow-K if you are taking this type of medicines.

Inform your doctor if you are taking any of the following medicines:

- digoxin - for heart problems
- medicines used to treat high blood pressure such as:
 - "ACE inhibitors" (such as lisinopril or captopril)
 - angiotensin-II receptor antagonists (such as valsartan or losartan)
 - beta-blockers (such as atenolol or bopindolol)
- medicines affecting your immune system such as ciclosporin
- medicines for the treatment of inflammation or pain such as "Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)" such as indomethacin
- medicines for thinning the blood such as heparin
- medicines called "anti-cholinergics", which are used to treat a variety of conditions, such as digestive system cramps, muscle or bladder spasms, asthma, motion sickness, treatment of some forms of poisoning or to help keep you asleep during an operation
- proton pump inhibitors such as omeprazole or pantoprazole, used to treat hyperacidity in the stomach
- other medicines such as direct renin inhibitors (e.g., aliskiren), used to treat hypertension

If you are taking any of the medicines listed above (or if you are not sure), consult the doctor or pharmacist before taking Slow-K.

⚠ Use of medicines and food

It is important to drink plenty of fluid throughout the day (e.g. tea, coffee, water) while under treatment with Slow-K.

⚠ Pregnancy and breast-feeding

If you are pregnant, your doctor will only prescribe the medicine for you if its use is very necessary.

Slow-K is a tablet with a special prolonged-release system that releases the medicine over time and the dissolving process takes a long time. In pregnant women, the digestive system works more slowly and it will therefore take longer for the medicine to pass through this system. Therefore, you may not receive the desired potassium dose from the Slow-K tablets.

Do not take this medicine when breast-feeding, unless the doctor decided that the benefit to the woman exceeds the risk to the baby.

If you are pregnant, think you are pregnant, are planning a pregnancy or are breast-feeding, consult the doctor before using the medicine.

⚠ Driving and using machines

Slow-K has no known effect on the ability to drive and use machines.

⚠ Important information about some of the ingredients of the medicine

Do not take this medicine if you have been told by your doctor that you cannot tolerate or digest some sugars. Slow-K contains sucrose (a type of sugar).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The doctor may suggest a higher or lower dosage. The usual dosage is generally:

To prevent low levels of potassium: 2 to 3 tablets each day.

To treat low levels of potassium: 5 to 6 tablets each day. The maximal dose: 12 tablets each day.

Do not exceed the recommended dose.

Do not take a larger amount, and do not take more often than recommended by the doctor.

If you have to take a total dose of 3 or more tablets each day, split them up so that you can take them with breakfast, lunch and dinner. If you have to take only 1 or 2 tablets each day, you can take them together with whichever meal is best for you.

How to take

- Take this medicine by mouth
- Swallow the tablets whole with a full glass of water or other liquid, during a meal, when sitting upright
- Do not crush, chew or suck the tablet, since it will affect their special prolonged-release system

Refer to a doctor if you have trouble swallowing the tablets, or if they seem to stick to your throat, since this could cause irritation that might lead to ulcers in your food pipe.

Duration of treatment

Keep taking this medicine until your doctor tells you to stop. It is important to keep up the level of potassium in your body.

Tests and follow-up

If you have heart or kidney problems, if you are over the age of 65 or if you are taking Slow-K for a long time, the doctor will perform certain tests during the course of your treatment. The levels of potassium and other substances in your blood will be measured in these tests. You heart will also be checked.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. You may feel light-headed or have an uneven heart beat.

If you forget to take Slow-K

Taking the medicine at the same time every day will help you remember when to take the medicine.

- If you forget to take the medicine at the scheduled time, take it as soon as you remember.
- However, if it is nearly time to take the next dose, skip the forgotten dose and consult the doctor.
- Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

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

4. SIDE EFFECTS

As with any medicine, use of Slow-K may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately, if you suffer from:

- diarrhea that is black or blood-stained
- irritable bowel, marked nausea or vomiting, severe stomach pain or wind, risk of ulceration; obstruction, hemorrhage or perforation of the gastrointestinal tract

Additional side effects

Report to a doctor if the following side effects occur (side effects of unknown frequency):

- itchy skin rash
- urticaria (a skin disease)
- high blood potassium levels (hyperkalemia) can develop in patients suffering from difficulties secreting potassium through the kidneys or with metabolic problems
- if you have a heart or kidney problem and you are concerned that it is getting worse. This can be caused by increased potassium levels in your body

Refer to the doctor if any of the above mentioned effects occur to you.

If after taking Slow-K you notice what appears to be a whole tablet in your stool, there is no reason for concern. Your body has absorbed the required amount of potassium and it is the tablet coating that has been expelled.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting of side effects:

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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.

Store below 30°C.

Protect from moisture.

Store in the original package.

Keep the box closed tightly.

Shelf life after first opening: 60 days.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Sucrose, talc, cetostearyl alcohol, gelatin, acacia, magnesium stearate, titanium dioxide, dispersed buff 70753 (titanium dioxide, iron oxide yellow, iron oxide red), carnauba wax.

Each tablet contains approximately 97 mg sucrose.

What the medicine looks like and the contents of the package

A sugar-coated, round, biconvex, light orange tablet.

The tablets are packaged in a plastic container which contains 100 tablets.

Registration holder:

Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

Manufacturer and address:

Sandoz Grup, Gebze, Turkey
for Novartis Pharma AG, Basel, Switzerland.

This leaflet was checked and approved by the Ministry of Health on: 29.06.2016

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 115 88 22133