Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Kalinor-retard 600 mg
Prolonged-release hard capsules

Active ingredient
Each capsule contains 600 mg potassium chloride
Potassium content, 315 mg, corresponds to 8 mmol = 8 mval K^+.

Inactive ingredients and allergens: See section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?
For prophylaxis and treatment of low blood potassium levels (hypokalaemia).
Therapeutic group: mineral/potassium for normalisation of potassium balance.

2. Before using this medicine
Do not use this medicine if:

- You are sensitive (allergic) to potassium chloride or to any of the other ingredients in this medicine (see section 6).
- In case of diseases that are commonly linked to an increase in blood potassium level above the normal level (hyperkalaemia):
  - restricted excretory kidney function (reduced excretion capability of the kidneys)
  - dehydration (lack of body water as a result of disruption of the water-salt balance)
  - Addison's disease (primary adrenal insufficiency, inadequate function of the adrenal gland cortex)
  - Adynamia episodica hereditaria (Gamstorp disease, a rare congenital disease with attacks of flaccid paralysis with elevated blood potassium concentration)
  - sickle cell anaemia (a disorder of haemoglobin formation)
  - metabolic imbalances in the acidic range, e.g. diabetic acidosis (hyperacidity of the blood in case of diabetes)
- In case of an elevated blood potassium level due to passage of potassium from the intracellular to the extracellular space, i.e. from the cells to the blood.

Special warnings about using this medicine
Talk to your doctor or pharmacist before taking Kalinor-retard 600 mg.
Talk to your doctor if you do not feel better or if you feel worse after several days.

Particular caution is required when using Kalinor-retard 600 mg:
Prescription of this preparation will be carefully considered by your doctor if you have a known impairment of the oesophagus or the gastrointestinal tract, such as narrowing of the oesophagus, stomach or intestine, or diseases associated with taking specific medicines (such as anticholinergics that work similarly to atropine from belladonna). These medicines may cause a deceleration in further transport of a bolus, as well as transport of medicines through the stomach and intestine.
Prior to use, mineral and acid base balances (electrolyte and acid-base status), cardiac rhythm and kidney function, particularly in elderly patients, should be checked. These values should be monitored during treatment, initially in shorter intervals and later in longer intervals.

Children and adolescents

Kalinor-retard 600 mg is not intended for use in children and adolescents.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.
Kalinor-retard 600 mg should be used with caution in case of simultaneous treatment with:
- medicines that work similarly to atropine (from belladonna) (anticholinergics)
- potassium-sparing diuretics
- medicines containing corticosteroid-suppressing substances (aldosterone antagonists)
- certain blood pressure-reducing medicines (ACE inhibitors, angiotensin II receptor blockers)
- medicines that may be harmful to the kidneys, such as certain medicines for pain relief and treatment of rheumatism (non-steroidal anti-inflammatory drugs amongst others).

Interaction with the aforementioned medicines, suddenly occurring hyperacidity of the blood *(*acidosis*),* sudden impairment of kidney function or other conditions may lead to an incidental increase in blood potassium concentration above the normal level (hyperkalaemia).
An increase in blood potassium concentration above the normal concentration reduces the effect of cardiac glycosides. In case of simultaneous treatment with specific blood pressure-reducing medicines (angiotensin-converting enzyme inhibitors/ACE inhibitors, angiotensin II receptor blockers), aldosterone antagonists (effect of corticosteroid-suppressing substances), potassium-sparing diuretics or certain medicines for pain relief and treatment of rheumatism (non-steroidal anti-inflammatory drugs and peripheral analgesics), such as indomethacin, a special examination of blood potassium values is indicated, as the aforementioned substances can lead to a reduction in excretion of potassium via the kidneys, and therefore an increase in blood potassium concentration above the normal concentration.
Anticholinergics (medicines that work similarly to atropine from belladonna) inhibit the movement processes in the intestine (intestinal motility), and therefore increase the (low) likelihood of side effects in the stomach and intestine in case of simultaneous use. Please note that this information may also apply to medicines used recently.

Using this medicine and food, drinks and alcohol
No interactions between Kalinor-retard 600 mg and substances, food or drinks are expected.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, or if you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There is no information on harmful effects during pregnancy and breast-feeding.

Driving and using machines
Taking Kalinor-retard 600 mg is not expected to affect your ability to drive, your reaction capacity or your general ability to act, even when using machines or working without secure support.

Important information about some of this medicine's ingredients
Kalinor-retard 600 mg contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per capsule, i.e. it is considered "sodium free".

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
The dosage depends on the extent of potassium deficiency to be balanced and will be adapted personally for you by your doctor.
The recommended dosage is usually:
For prophylaxis of potassium deficiency in general, 2-3 capsules of Kalinor-retard 600 mg daily (corresponding to 16-24 mmol K^+).

For treatment of potassium deficiency in general, the recommended dosage is 2-4 capsules of Kalinor-retard 600 mg (corresponding to 16-32 mmol K^+), 2-3 times per day. Overall 4-12 capsules of Kalinor-retard 600 mg daily (corresponding to 32-96 mmol K^+). Your doctor will adapt the dosage to your personal potassium requirement.

Method of administration
The capsules should be swallowed whole at mealtimes with plenty of fluid (at least a full glass of water). If you have difficulties swallowing the capsules, the two halves of the capsule can be pulled apart and the contents taken from a spoon. Do not forget to drink plenty of fluid (at least a full glass of water).

Do not exceed the recommended dose.

Treatment duration
Continued administration of Kalinor-retard 600 mg is recommended for as long as the cause of potassium deficiency persists. In other cases, days to weeks often suffice to balance the potassium deficiency.

Please consult your doctor or pharmacist if you think that the effect of Kalinor-retard 600 mg is too strong or too weak.

If you have accidentally taken an overdose of the medicine
Excess potassium is rapidly excreted by normally functioning kidneys. Therefore, a harmful excessive increase in blood potassium concentration is to be expected only in case of a significant overdose. As the normal function of the heart is impaired in case of excessively elevated blood potassium concentrations, you should see a doctor immediately in case of a significant overdose. The blood potassium concentration can be measured by the doctor in a laboratory test and/or the cardiac rhythm can be checked using an ECG. If necessary, the doctor can normalise the heart function and the blood potassium concentration using suitable measures. In case of only mildly elevated blood potassium concentration, normalisation can occur through normal potassium excretion via the kidneys and without further treatment.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine at the scheduled time
Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine
If you should take Kalinor-retard 600 mg to control potassium deficiency or to prevent the occurrence of potassium deficiency, intake of potassium through Kalinor-retard 600 mg is necessary to maintain balanced potassium levels. Without taking this additional potassium, your intake of potassium through food is inadequate to cover your current potassium requirement. If you interrupt taking Kalinor-retard 600 mg or stop taking it prematurely, you may develop potassium deficiency, which may have negative effects on your heart and the functioning of nerves and muscles.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

<u>4. Side effects</u>
Like with all medicines, using Kalinor-retard 600 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using this medicine and consult your doctor immediately in case of:

- severe vomiting, severe abdominal pain and gastrointestinal bleeding. Your doctor will decide what to do next.
- rare: allergic reactions, such as eczema, irritation, rash.

Uncommon side effects - affect 1-10 in 1,000 users

- Occasionally upper abdominal and intestinal symptoms, nausea, vomiting and diarrhoea, heartburns, abdominal pain, hiccups, flatulence have been observed. Serious damage to the mucosa in the oesophageal and gastrointestinal tract region, which may occur as a result of severe vomiting, severe stomach pains and gastrointestinal bleeding, for example, has not been observed for Kalinor-retard 600 mg to date.

Rare side effects - affect 1-10 in 10,000 users

- hyperkalaemia (excess potassium in blood)

Taking countermeasures for side effects

Nausea and other gastrointestinal symptoms stated above, which are actually related to taking Kalinor-retard 600 mg, require no special treatment. To avoid them, ensure that you take Kalinor-retard 600 mg with plenty of fluid and never on an empty stomach. Follow the information given under the "Method of administration" section.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/bottle. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C. Keep the bottle tightly closed.
- Shelf life after opening: 6 months.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Capsule core:
ethyl cellulose, magnesium stearate, sodium lauryl sulfate.
Capsule shell ingredients:
gelatine, titanium dioxide (E171), quinoline yellow (E104), erythrosine

What the medicine looks like and contents of the pack:

A hard gelatine two-part capsule (the upper capsule part is opaque yellow, the lower capsule part is opaque white) containing odourless white free-flowing pellets.
A glass bottle containing 20, 50 or 100 prolonged-release hard capsules.
Not all pack sizes may be marketed.

Registration holder's name and address: Trustpharm Ltd., 50 Hakishon St., Tel Aviv.
Manufacturer's name and address:

Desma GmbH, Peter-Sander Str.41b, 55252 Mainz-Kastel, Germany.

Approved in August 2022.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
170-46-36674-99