

### Patient Leaflet According to the Pharmacists' Regulations

#### (Preparations) - 1986

This medicine is sold with a doctor's prescription only

### Potassium Oral Solution

*Dilute the dose with 120 ml (about half a glass) of water or juice, and drink slowly*

#### Active ingredient:

Each 5 ml contains 1.4 g potassium gluconate and 0.43 g potassium citrate which are 10 milliequivalents (mEq) potassium ions K<sup>+</sup>.

The amount of potassium ions (K<sup>+</sup>) in the solution and in comparison to a tablet containing 600 mg potassium chloride

Name of the product	Dosage unit	Milligrams (K <sup>+</sup> )	Milliequivalents
Potassium Oral Solution (Rafa)	5 ml	390 mg	10 mEq
Potassium Chloride 600 mg	1 tablet	312 mg	8 mEq

Each 5 ml of potassium oral solution (Rafa) are equivalent to 5 ml potassium chloride solution 15%.

For a list of inactive ingredients, please see section 6. Also see 'Important information about some of the medicine's ingredients' in section 2.

#### Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to 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 the medicine intended for?

This medicine is intended for the prevention and treatment of low blood potassium levels – hypokalemia.

#### Therapeutic group:

Potassium supplement.

#### 2. Before you take the medicine

##### Do not use this medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (for a list of inactive ingredients, please see section 6).
- Do not use this medicine if you suffer from a high level of blood potassium – hyperkalemia, or other conditions that increase the risk of hyperkalemia such as adrenal gland insufficiency, severe dehydration, acute metabolic acidosis, extensive tissue breakdown, unbalanced diabetes and/or chronic kidney failure.

#### Special warnings regarding the use of this medicine:

- During the treatment with this medicine do not consume a low salt diet, do not use salt

substitutes and do not start strenuous physical exercise.

- If during the treatment you experience severe or prolonged diarrhea (that can cause severe dehydration among other things) refer to your doctor immediately.
- If the medicine is administered during diarrhea, blood potassium levels should be monitored.

#### Before the treatment with the medicine tell your doctor:

- If you suffer from familial periodic paralysis or from myotonia congenita (congenital muscle disease), or from high levels of creatinine in the blood.
- If you suffer or have suffered in the past from impaired function of the: heart, kidneys/urinary system or the digestive system (such as obstruction or narrowing, delayed gastric emptying, ulcer).

#### Possible interactions with other medicines which are taken concomitantly:

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Digitalis (such as digoxin for the treatment of heart problems).
- Steroids, corticotrophin hormone (ACTH), amphotericin B, antibiotics such as: gentamicin, polymyxin B or antibiotics of the penicillin group.
- Medicines for the reduction of blood pressure and for heart problems such as ACE inhibitors, beta blockers.

- Heparin (an anticoagulant medicine), ciclosporin.
- Non-steroidal anti-inflammatory drugs (NSAIDs).
- Medicines that contain potassium, diuretics which cause potassium accumulation.
- Diuretics of the thiazide group, laxatives.
- Calcium salts that are not orally administered.
- Sodium bicarbonate and exchange resins.
- Insulin.
- Medicines with an anticholinergic activity.
- Blood transfusions.

**Use of this medicine and food:** the medicine should be taken with food or immediately after food. Ensuring that, reduces the risk of digestive system side effects. See also special warnings.

**Pregnancy and breastfeeding:** if you are pregnant or breastfeeding, consult your doctor before using this medicine.

**Use in the elderly:** this population may be at higher risk for hyperkalemia, due to changes in the ability of the kidneys to excrete potassium.

**Important information about some of the medicine's ingredients:** each 5 ml contains 5 mg sodium saccharin, 8.5 mg sodium cyclamate and 100 mg ethanol.

#### 3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and the manner of treatment will be determined by the doctor only. The dose will be adjusted for you according to your condition and your reaction to the treatment. Use the medicine at set intervals as determined by the attending doctor. Dilute the dose well with water or juice (please see below 'Directions for use').

#### Do not exceed the recommended dose.

#### Directions for use:

- Do not inject. The solution is intended for drinking.
- Dilute the dose well with 120 ml (about half a glass) of water or juice and drink slowly (throughout 5 to 10 minutes), according to the doctor's instructions.
- Take the medicine with food or immediately after food.
- Use a measuring cup or syringe to measure the correct amount of the medicine. Do not use a household spoon to measure the amount of medicine since household spoons vary in size and you might not take the correct amount of the medicine.
- The bottle has a child resistant cap. Child resistant caps have significantly reduced the number of cases of poisoning caused by medicines.

#### Attention:

- During the treatment with this medicine do not consume a low salt diet or use salt substitutes, as salt substitutes ('low sodium salt') usually contain potassium.
- Do not start strenuous physical exercise during the treatment.

**Tests and follow up:** During the treatment with this medicine it is recommended to undergo

blood potassium level tests, blood pH tests, kidney function tests and ECG.

**If you have accidentally taken a higher dosage:** if you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

**If you forget to take this medicine:** if you remember within two hours of the time you were supposed to take the medicine - take it immediately as you remember and afterwards, return to your regular administration times. If you remember after more than two hours from the time you were supposed to take the medicine - skip the forgotten dose and return to your regular administration times. Do not take two doses together!

Continue with the treatment as recommended by your doctor. Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor or a pharmacist. Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

#### 4. Side effects:

Like any medicine, the use of this medicine may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

#### Stop the treatment and refer to your doctor immediately in the following cases:

- With the appearance of hyperkalemia which can be manifested by severe muscle weakness, unusual tiredness or weakness, slow or irregular heartbeat, confusion, tingling sensation/

numbness of the limbs or lips, unexplained anxiety, shortness of breath or difficulty breathing.

**Refer to a doctor immediately in the following cases:** With the appearance of irritation of the digestive system which may occur if the solution passage is delayed, or if it comes in contact with ulcers. The symptoms include: cramps or prolonged abdominal pain, throat or chest pain especially when swallowing, blood in the stools.

#### Additional side effects:

Diarrhea, nausea, vomiting, flatulence, abdominal pain or discomfort. These side effects may occur more often if the medicine is not diluted properly or not taken with food.

If the side effects persist, or they are bothersome or get worse, consult your doctor.

#### Side effects and drug interactions in children and infants:

Parents should inform the attending doctor of any side effect and any other medicine given to the child. See above for details of side effects and interactions with other medicines.

In any case you experience side effects not mentioned in this leaflet or if you feel a change in your general feeling, consult your doctor immediately!

#### 5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

- Storage conditions: Store below 25°C.
- After first opening, it may be used for 6 months.

#### 6. Additional information

##### In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Ethanol, citric acid, sodium cyclamate, saccharin sodium, tutti frutti flavor, methyl hydroxybenzoate, propyl hydroxybenzoate, purified water.

##### What does the medicine look like and what does the package contain?

200 ml colorless solution in a brown plastic bottle.

**Registration holder:** Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301

**Medicine registration number in the National Medicine Registry of the Ministry of Health:** 1123929512

This leaflet was checked and approved by the Ministry of Health in February 2014.

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