

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

This medicine is dispensed with a doctor's prescription only

**Micro Kalium
Prolonged release capsules**

600 mg

Active ingredient:

Each capsule contains:

Potassium chloride 600 mg

For inactive ingredients, please refer to section 6- "Additional Information".

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

Micro Kalium is not intended for children and adolescents under the age of 18.

1. What the medicine is intended for?

For the treatment or prevention of low levels of potassium in the blood (hypokalemia).

Additional intake of potassium can be necessary in patients who either do not get enough potassium through usual diet, or who have lost too much potassium due to a disease or treatment with certain medicines.

The intake of too much potassium can lead to health problems as well. Therefore, it is important to take this medicine exactly according to your doctor's instructions.

Micro Kalium capsules contain potassium chloride. It has a slow-release system that releases your medicine evenly throughout the day.

Therapeutic group

Potassium supplement

2. Before using the medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient (potassium) or to any of the other ingredients this medicine contains (please refer to section 6- "Additional Information").
- you are hypersensitive to the administration of potassium, e.g. if you suffer from a disease called Adynamia episodica hereditaria (a congenital disease with suddenly appearing attacks of flaccid paralysis as well as increased potassium blood levels during such an attack) or Eulenburg disease (a congenital disease with muscular rigidity followed by flaccid paralysis of musculature, especially during physical exercise or in the cold).
- there is too much potassium in your blood (e.g. due to severe burns or strong dehydration), as additional administration of potassium may lead to cardiac arrhythmias and even to cardiac arrest.
- you suffer from one of the following diseases:
 - adrenal gland insufficiency (Addisons' disease), which is not treated
 - adrenocortical disease (hyporeninemic hypoaldosteronism)
 - metabolic acid excess in your blood (decompensated metabolic acidosis)
 - disorders of the stomach or intestinal passage or narrowing in the gastrointestinal area

- narrowing or misplacement of the oesophagus (also caused by tumours of surrounding organs, extension of the main artery near by the oesophagus, ventricular enlargement or after surgeries in this area)
- pronounced renal insufficiency (also without increased potassium level in the blood)
- you take certain other medicinal products, especially potassium-sparing diuretics (spironolactone, triamterene, amiloride) at the same time.

Special warnings regarding the use of the medicine

Before treatment with **Micro-Kalium, tell the doctor if:**

- you have a stomach or intestinal disease, as the intake of **Micro-Kalium** may irritate the gastrointestinal mucosa. Please consult your doctor in such a case.
- you experience pronounced nausea or vomiting, severe abdominal pain, excessive flatulence or diarrhoea with black and/or bloody stool during treatment with **Micro-Kalium**. Stop taking this medicine and talk to a doctor immediately.
- the function of your kidneys is impaired, you have a heart condition or you take **Micro-Kalium** over a long period of time. In such cases your doctor will regularly check your blood to control its salt concentration.
- you have an acid excess in your blood (metabolic acidosis). In such case, potassium deficiency is not treated with potassium chloride, but with alkalisating potassium salts (e.g. with potassium bicarbonate).
- you are on a low-salt or low-sugar diet or if you consume liquorice regularly. In such cases your doctor will regularly check your blood to control its salt concentration. Furthermore, avoid sudden changes in your dietary habits.

Children and adolescents

Micro-Kalium should not be used in children and adolescents under the age of 18 as safety and efficacy have not been established.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist,

especially if you are taking:

Certain medicines may increase an excess of potassium:

- ACE inhibitors and beta-blockers (antihypertensive medicines),
- digoxin (medicines for the treatment of heart failure and cardiac arrhythmias),
- anti-inflammatory / analgesic medicines (e.g. indomethacin),
- heparin (a blood-thinning medicine).

Potassium-sparing diuretics (spironolactone, triamterene, amiloride) should not be taken together with **Micro-Kalium**.

Take special care with the concomitant use of anticholinergics (which affect the autonomic nervous system) as they may reduce the activity of the stomach and intestines.

Use of the medicine and food:

Take the capsules with or after a meal, with plenty of water.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

As during pregnancy gastro-intestinal function is slightly reduced, **Micro-Kalium** should only be taken after explicit medical advice.

Breast-feeding

If prescribed by a doctor, use during breast-feeding is possible.

Driving and using machines:

Taking Micro-Kalium prolonged release capsules is not expected to affect the ability to drive and use machinery

3. How should you use the medicine?

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment. The dosage and manner of treatment will be determined by the doctor only.

The acceptable dosage is usually:

To prevent low levels of potassium (hypokalemia):

2 to 3 capsules each day.

Prevention of potassium deficiency may be necessary during treatment with certain medicines which increase potassium excretion.

To treat low levels of potassium (hypokalemia):

2 to 4 capsules, two to three times a day. Overall 4-12 capsules a day.

The maximum daily dose is 12 capsules each day.

If you are concomitantly treated with diuretic medicines, that you need to take every other day, the doctor will advise you to take Micro kalium on those days when you are not taking the diuretics.

Do not exceed the recommended dose.

Do not take more capsules than you are told to or take them more often.

Duration of administration

The doctor will decide on the duration of treatment.

Method of administration

Take the capsules with or after a meal, with plenty of water.

Capsules must not be chewed or sucked.

The capsule should not be opened and its contents dispersed since it contains components which may swell up.

If you accidentally took a higher dose

Signs of overdose primarily affect heart and circulation (e.g. dizziness, shock, cardiac arrhythmia) as well as musculature and nerves (e.g. sensory disturbances, seizures, breathing difficulties). However, a dangerous increase in blood potassium can also occur without signs. In case of suspected overdose, if you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of medicine with you.

If you forgot to take the medicine

If you forgot to take one dose, continue with the next dose as usual. Do not take a double dose to compensate for a forgotten dose.

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

If you stop taking the medicine your potassium level may drop again.

Please talk to your doctor or pharmacist if you have the impression that the effect of this medicine is too strong or too weak.

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side effects

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

Effects that require special attention:

Tell your doctor immediately if you experience any of the following side effects:

Very rare side effects (may affect up to 1 in 10,000 users)

- Intestinal obstruction or bleeding and ulcers in the gastrointestinal tract. If you experience pronounced nausea or vomiting, severe abdominal pain, excessive flatulence or diarrhoea with black and bloody stool during treatment with **Micro-Kalium**, stop taking this medicine and talk to a doctor immediately (see also section 2 "Special warnings regarding the use of the medicine").

Other possible side effects are:

Rare side effects (may affect 1 to 10 in 10,000 users)

- Nausea, flatulence, vomiting, abdominal pain and diarrhoea. These effects are caused by mucosal irritation of the gastro-intestinal tract and usually decrease when taking **Micro-Kalium** with plenty of water as well as taking it during or after a meal, or after reducing the dose.
- Itching, rash, hives

Side effects whose frequency is unknown (effects whose frequency has not yet been determined):

If renal excretion is impaired, blood potassium levels can become too high (hyperkalaemia). The signs are similar to those of an overdose (see also section 3 "If you accidentally took a higher dose").

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, you must consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) which 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?

- Store below 25°C.
- 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 this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

- Do not throw away any medicines via wastewater or household waste. Ask your 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, the medicine also contains:

Ethylcellulose, gelatin, talc, erythrosine (E127), titanium dioxide (E171), ferric oxide black (E172).

What the medicine looks like and the contents of the pack:

Micro-Kalium prolonged-release capsules are maroon opaque hard capsules.

Micro-Kalium is available in blister packs of 50 capsules.

Manufactured by: G.L. Pharma GmbH, Industriestrasse 1, A-8502 Lannach, Austria

Marketing Authorisation Holder and Importer:

A.L.Medi-Market Ltd, 3 Hakatif street, Emek Hefer Industrial Park, 3877701

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

170-47-36215-00

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