PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Kaluril

Tablets

Composition
Each tablet contains:
Amiloride (as Hydrochloride anhydrous) 5 mg
Hydrochlorothiazide 50 mg
For information regarding inactive ingredients and allergens, see section 2 – "Important information about some ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Kaluril is intended for treatment of hypertension, with or without other medicines, as well as for treatment of edema associated with congestive heart failure and hepatic cirrhosis.

Therapeutic class
Both active ingredients are diuretics. This group acts by increasing the amount of urine excreted from the body, which lowers blood pressure or removes excess water from the body.
Amiloride: a potassium-sparing diuretic.
Hydrochlorothiazide: a thiazide diuretic.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:
- You are sensitive (allergic) to hydrochlorothiazide or to amiloride hydrochloride or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You are suffering from diabetes (high blood sugar level).
- You have been told by your doctor that you have high levels of urea, creatinine, potassium or calcium in your blood.
- You are sensitive to acetazolamide, a diuretic that is used for eliminating fluids from your body and for treatment of elevated intraocular pressure (glaucoma), heart problems and sometimes seizures or epilepsy.
- You are sensitive to a type of antibiotic called sulfonamides, such as sulfamethoxazole.
- You are sensitive to another thiazide diuretic.
- You are taking potassium-sparing diuretics such as eplerenone, spironolactone or triamterene.
- You are taking potassium supplements or medicines that contain potassium, or you eat potassium-rich foods.
- You have a kidney disease, urinary retention or liver disease.
- You have Addison's disease (adrenal insufficiency).
- You are taking medicines containing Lithium concomitantly.

Do not take Kaluril if any of the above conditions applies to you. If you are unsure, consult with your doctor or pharmacist before taking this medicine.

Special warnings regarding the use of the medicine
Before treatment with Kaluril, inform the doctor if:
- You have previously had skin cancer, or if you develop an unexpected skin lesion while using the medicine. Using hydrochlorothiazide may increase the risk for developing cancer in the skin and lips (non-melanoma skin cancer), particularly during long-term use with high doses. The skin should be protected from exposure to the sun and to ultraviolet (UV) radiation while using Kaluril.
- You have previously experienced breathing or lung problems (including inflammation or fluid in the lungs) as a result of taking hydrochlorothiazide. If you develop severe shortness of breath or breathing difficulties after taking Kaluril, seek medical attention immediately.
- You experience a decrease in vision or have eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase in intraocular pressure, and can happen within hours to a week of taking Kaluril. This can lead to permanent vision loss, if not treated. If you have had a penicillin or sulfonamide allergy in the past, you may be at a higher risk of developing this.
- You are elderly, dosage adjustment may be required depending on your kidney function and clinical reaction.
- You have been told by your doctor that you have high levels of uric acid, cholesterol or triglycerides (a type of cholesterol) in your blood.
- You are taking digitalis such as digoxin (used for treatment of heart failure or arrhythmia).
- You are being given intravenous fluids (through a tube inserted into one of your veins).
- You have recently had severe vomiting or diarrhea.
- You have lupus.
- You have gout.

If you are not sure, consult with your doctor or pharmacist before taking Kaluril.

Children and adolescents
Do not give this medicine to children and adolescents under the age of 18 years, as the safety and efficacy of using this preparation in children and adolescents have not been proven.

Tests and follow-up
- When you are taking this medication, it may affect certain blood and urine tests. Remind your doctor you are taking Kaluril if he refers you to undergo any test.
- If you have diabetes or your doctor suspects you have diabetes, you may need to undergo some tests before receiving treatment with Kaluril.
- Due to the risk of hyperkalemia, use with caution and monitor serum potassium levels frequently, when taken concomitantly with any other medical preparation known to cause high levels of potassium.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. This is because Kaluril may affect the way some other medicines work. Also, certain medicines may affect the way Kaluril works. It is important to tell your doctor or pharmacist, especially if you are taking:
- Angiotensin converting enzyme inhibitors (ACE inhibitors) such as enalapril – used to treat high blood pressure or heart problems.
- Angiotensin II receptor antagonists such as losartan – used to treat hypertension or diabetes with kidney damage.
- Other medicines for the treatment of hypertension.
- Medicines for diabetes, such as insulin or chlorpropamide.
- Lithium – for treating depression.
- Non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen – used to reduce high temperature (fever), pain or for arthritis.
- Barbiturates – used to induce sleep or to reduce anxiety.
- Analgesics, such as: codeine, dihydrocodeine, dextropropoxyphene, diamorphine, morphine, pentazocine and pethidine.
- Cholestyramine and colestipol – used to treat high cholesterol (hyperlipidemia).
- Steroids – used to treat many different conditions, such as: rheumatism, arthritis, allergies, skin problems, asthma or a type of blood disorder.
- ACTH – to test whether your adrenal glands are working properly.
- Medicines injected for treatment of allergic reactions, such as adrenaline (also known as epinephrine).
- Tacrolimus – used after a liver or kidney transplant to prevent rejection of the transplanted organ.
- Ciclosporin – used for treatment of rheumatoid arthritis or to prevent rejection after a transplant.
- Certain muscle relaxants, such as tubocurarine.
- Trilostane – used to treat breast cancer or overactive adrenal glands (such as in Conn's syndrome and Cushing's syndrome).

In addition, if you are about to undergo an operation, make sure the treating doctor is aware that you are taking Kaluril.
If you are not sure if any of the above applies to you, consult with the doctor or pharmacist before taking Kaluril.

Use of the medicine and food
Your doctor may ask you to change your diet slightly and to avoid certain foods which contain a lot of potassium. These foods include milk, bananas, raisins and prunes. Your doctor will instruct you which types of foods you should avoid; consult with your doctor before taking Kaluril tablets.

Use of the medicine and alcohol consumption
Your doctor may instruct you to keep your alcohol intake at a minimum while taking Kaluril. Alcohol may increase the effect of Kaluril so that you may feel lightheaded when standing up quickly.

Pregnancy and breastfeeding
Pregnancy
Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant. Usually, your doctor will advise you to take another medicine instead of Kaluril, as Kaluril is not recommended during pregnancy. This is because Kaluril crosses the placenta and its use after the third month of pregnancy may be harmful to the fetus and neonate.
Breastfeeding
Tell your doctor if you are breastfeeding or about to start breastfeeding. Kaluril is not recommended for breastfeeding mothers.

Driving and operating machinery
This medicine may cause tiredness or dizziness. Do not drive or operate machinery before consulting with your doctor or before you know how the medicine affects you.

Important information about some of the ingredients of the medicine
- Kaluril contains lactose. If you have been told by your doctor that you have an intolerance (sensitivity) to some sugars, consult with your doctor before taking this medicine.
- This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.
- This medicine contains the colorant sunset yellow FCF, which may cause allergic reactions.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:
- **For high blood pressure:** starting dosage of half a tablet of Kaluril given once a day. If necessary, it can be increased to one tablet given once a day or in divided doses.
- **For heart failure and hepatic cirrhosis:** starting dosage of half a tablet of Kaluril given once a day; afterwards, the dosage can be adjusted if necessary, but do not exceed two tablets of Kaluril per day.
- **For edema associated with hepatic cirrhosis:** start treatment with a low dosage. Increase gradually from a single dosage of one Kaluril tablet until effective urine output is achieved. Do not exceed two tablets of Kaluril per day.

This medicine should be taken at set intervals as determined by the treating doctor.
Consult with the doctor regarding correct diet during the treatment (e.g. use of salt or salt substitutes).
It is recommended to take the tablet in the morning, as the preparation may cause excessive urination.
Do not exceed the recommended dose.
Note!
Wait 2-4 hours between taking this medicine and taking a medicine containing cholestyramine or colestipol.
Method of use
- Take this medicine orally.
- There is no information regarding crushing or chewing of the tablet.
- The tablet can be halved on the score-line.
- The tablet should be swallowed with some water.

If you accidentally took a higher dosage
If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
If you forgot to take the medicine
If you forgot to take this medicine at the scheduled time, skip the forgotten dose and take the next dose at the usual time. Do not take two doses together to compensate for a forgotten dose.
Adhere to the treatment as recommended by your doctor.
If you stop taking the medicine
Do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Kaluril 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.
The following side effects may appear when using Kaluril:
Stop taking Kaluril and contact your doctor immediately if you notice any of the following severe side effects that may occur. You may require urgent medical care:
- Allergic reactions – the symptoms may include blood vessel inflammation, difficulty breathing or swallowing, fainting, redness, blisters, peeling skin, muscle pain, chills, general malaise, ulcers in the mouth, eyes or genitals
- Irregular heartbeat which may lead to fainting and dizziness, palpitations
- Fast heartbeat, chest pain (angina pectoris)
- Intestinal bleeding – symptoms may include blood in the stool or darker stool
- Liver problems such as jaundice – symptoms may include yellowing of the skin and/or the white part of the eyes

Additional side effects:
Allergic reactions
- Purplish or reddish spots, skin irritation, increased sensitivity to sunlight and a nettle-like rash (allergic rash)

Heart and circulation
- Feeling lightheaded when standing up quickly

Blood
- Anemia – symptoms include unusual tiredness or loss of color in the lining of the eyes and the skin around the eyes
- Other blood disorders which can result in high temperature (fever), a sore throat, being unable to stop bleeding from a cut
- Changes in the levels of various chemicals in the blood, which are usually detected in blood or urine tests

Stomach and digestive system
- Nausea or vomiting, digestive difficulties, diarrhea, constipation, stomach ache and stomach cramps, flatulence, bloated feeling, hiccups
- Inflammation of the pancreas (pancreatitis) – symptoms may include nausea and vomiting with pain in the stomach and back area
- Swelling of the salivary glands
- Dry mouth
- Feeling of thirst
- Bad taste in the mouth
- Reduced appetite or loss of appetite

Chest
- Breathing difficulties
- Nasal congestion
- Cough
- Very rare: acute respiratory distress syndrome (signs include severe shortness of breath, fever, low blood pressure, muscle weakness and confusion)

Nervous system
- Dizziness, feeling as if you are spinning (vertigo), prickling and tingling sensation
- Drowsiness or sometimes a feeling that you cannot fall asleep
- Stupor, a type of brain disorder called encephalopathy
- Nervousness, confusion, depression or restlessness
- Tremors
- Headache, forgetfulness

Skin and hair
- Flushing, sweating
- Skin rash, itch
- Hair loss
- Skin and lips cancer (a non-melanoma skin cancer)

Eyes and ears
- An increase in intraocular pressure, which is usually discovered during eye examinations
- Changes in vision
- Decrease in vision or eye pain due to high pressure [possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute closed-angle glaucoma]
- Ringing in the ears

Joints and muscles
- Joint pain, pain in the fingers and toes, gout
- Neck, shoulder and back pain
- Leg pain, muscle cramps

Urinary tract
- Difficulty or pain while urinating, an increase in the amount of urine passed
- Contractions of the bladder which may lead to an increase in urination frequency
- Kidney problems which may lead to a reduced amount of urine passed
- Urination at night, urinary incontinence

Sexual
- Reduced libido
- Impotence

General/other side effects
- General malaise, tiredness, weakness, dehydration

Side effects with unknown frequency (effects whose frequency has not yet been determined)
- Skin and lips cancer (a non-melanoma skin cancer)

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 your doctor.
Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- 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 an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (Exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place below 25°C, and in the original package to protect from light.**
- Do not discard medicines in the wastewater or domestic waste. Consult with your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:
Lactose monohydrate, dibasic calcium phosphate dihydrate, starch, sodium starch glycolate, color D&C yellow No. 10 aluminium lake, magnesium stearate, colloidal silicon dioxide, color FD&C yellow No.6 (Sunset yellow FCF) aluminium lake.
Each tablet contains:
71.4 mg lactose and 0.25-0.37 mg sodium.
What does the medicine look like and what are the contents of the package:
A yellow, round tablet with a score line on one side, and debossed with "TEVA" on the other side.
The package contains 30 tablets in a blister pack.
Name and address of the manufacturer and license holder:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.
The leaflet was revised in July 2024 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health:
117.57.23150

KALURIL PIL MW0724

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