

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

The medicine is dispensed with a doctor's prescription only

**Fosfomycin D.K.L.  
Powder for Oral Solution**

**Active ingredient:**

Each sachet contains: 3 g fosfomycin (as trometamol).

For the list of the additional ingredients, see section 6. See also 'Important information about some of this medicine's ingredients' in section 2.

**Read the entire leaflet carefully before you start using the 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 the 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 to yours.

**1. What is this medicine intended for?**

Fosfomycin D.K.L. is intended for:

- Treatment of acute uncomplicated infection of the urinary bladder (cystitis) in women and female adolescents.
- Preventive antibiotic treatment before taking a prostate tissue sample through the rectum (transrectal biopsy) in an adult man.

**Therapeutic group:** antibiotic.

Fosfomycin D.K.L. is an antibiotic that contains the active ingredient fosfomycin (as fosfomycin trometamol), which kills the bacteria that can cause infections.

**2. Before using this medicine**

**Do not use this medicine if:**

- |  |
|--|
| <ul style="list-style-type: none"><li>• You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (for the list of the additional ingredients, see section 6).</li></ul> |
|--|

**Special warnings about using this medicine:**

**Before using Fosfomycin D.K.L., tell your doctor if:**

- You suffer from recurrent and persistent infections of the bladder.
- You previously suffered from diarrhea after taking any other antibiotics.
- You suffer or have suffered in the past from impaired kidney function or are undergoing hemodialysis treatment.

**Additional warnings**

**Conditions requiring attention:**

This medicine can cause serious side effects. These effects include allergic reactions and inflammation of the large intestine. Pay attention to certain symptoms while you are taking this medicine, to reduce the risk of any problems. See 'Serious side effects' in section 4.

**Children and adolescents:**

This medicine is not intended for children under the age of 12, as the safety and efficacy of the medicine in this age group has not been determined.

**Interactions with other medicines:**

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- **Metoclopramide** (for treatment of nausea and vomiting) or other medicines that increase the movement of food through the digestive system, as they may reduce the absorption of the medicine in your body.
- **Anticoagulants**, as their ability to prevent blood clotting may be altered by taking Fosfomicin D.K.L. or other antibiotics.

**Using this medicine and food:**

Food may delay the absorption of this medicine, therefore the medicine should be taken on an empty stomach (2-3 hours before a meal or 2-3 hours after a meal).

**Pregnancy and breastfeeding:**

- If you are pregnant, think you are pregnant, are planning to become pregnant, or if you are breastfeeding, consult your doctor before using this medicine.
- If you are pregnant, the doctor will tell you to take the medicine only if it is clearly needed.
- Breastfeeding women can receive a one-time dose of the medicine, on the doctor's order. The medicine passes into the breast milk in small quantities.

**Driving and using machines:**

You may experience side effects such as dizziness, which may affect your ability to drive or operate machines.

Do not drive or operate machines if you feel dizzy or experience other side effects that might affect your ability to drive and/or operate machines.

**Important information about some of this medicine's ingredients:**

- *Sodium*: the medicine contains less than 23 mg of sodium per sachet, therefore is considered as "sodium-free".
- *Sucrose*: each sachet contains approximately 2.213 g sucrose. If you have intolerance to certain sugars, contact your doctor before taking this medicine.
- *Glucose*: included in the flavouring ingredients mandarin and orange.
- *Sulfites*: the medicine may contain sulfites at levels defined as safe, which in rare cases may cause severe hypersensitivity reactions and bronchospasm.
- *Saccharin*: each sachet contains approximately 16 mg saccharin.

**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. This medicine is not intended for children under the age of 12.

**The recommended dosage is usually:**

For treatment of acute uncomplicated infection of the urinary bladder in women and female adolescents - this medicine is administered as a one-time dose (one sachet of Fosfomicin D.K.L.).

For preventive antibiotic treatment in transrectal prostate biopsy - one sachet 3 hours before the procedure and one sachet 24 hours after the procedure.

### **Impaired kidney function**

Patients with severe impairment of kidney function or patients undergoing hemodialysis - the medicine should not be used, except after patient benefit-risk assessment by the doctor.

### **Children and adolescents**

This medicine is not intended for children under the age of 12.

### **Do not exceed the recommended dose.**

### **How to use this medicine:**

The medicine is intended to be administered orally.

Take the medicine on an empty stomach (about two to three hours before or after a meal), preferably before going to bed, after emptying the bladder.

Pour the entire contents of the sachet into a full glass of water, and mix well until the powder is dissolved. Drink the entire contents of the glass immediately.

After you take Fosfomycin D.K.L., improvement is to be expected within 2-3 days.

**If you have accidentally taken a higher dose:** 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.

Adhere to the treatment as recommended by your doctor.

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## **4. Side effects**

As with any medicine, using Fosfomycin D.K.L. may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

### **Serious side effects**

**Stop taking this medicine and consult your doctor immediately if one or more of the following symptoms occur during the treatment:**

- Anaphylactic shock, a type of life-threatening allergic reaction (*unknown frequency*). The symptoms include a sudden onset of rash, itching or hives on the skin and/or shortness of breath, wheezing or breathing difficulties.
- Swelling of the face, lips, tongue or throat with breathing difficulties (angioedema) (*unknown frequency*).
- Moderate to severe diarrhea, abdominal cramps, bloody stools and/or fever may indicate that you have an infection of the large intestine (antibiotic-associated colitis) (*unknown frequency*). Do not take medicines against diarrhea that inhibit intestinal motility.

## **Additional side effects**

### Common side effects (appear in 1-10 in 100 users):

Headache, dizziness, diarrhea, nausea, indigestion, abdominal pain, infection of the female genitalia with symptoms such as inflammation, irritation, itching (vulvovaginitis).

### Uncommon side effects (appear in 1-10 in 1,000 users):

Vomiting, rash, hives (urticaria), itching.

### Side effects of unknown frequency (the frequency of these effects has not been established yet):

Allergic reactions.

**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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or 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 your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

### **Storage conditions:**

Store below 25°C.

## **6. Additional information**

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

Sucrose, mandarin flavour, orange flavour, saccharin sodium.

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

White or almost white powder for preparation of an oral solution, in a single dose laminate sachet.

The sachet is a four-layer laminate of paper/polyethylene/aluminium/polyethylene.

The medicine is marketed in a cardboard packaging containing one sachet.

### **Manufacturer:**

Labiana Pharmaceuticals S.L.U., Spain

C/Casanova 27-31, 08757 Corbera de Llobregat (Barcelona) Spain

**Registration holder's name and address:** D.K.L. Pharma Ltd., Dizengof 253 St., Tel Aviv 6311708, Israel.

**Registration number of the medicine in the Ministry of Health's National Drug Registry:** 177-38-37641-99

Revised in October 2024 according to Ministry of Health guidelines.