PACKAGE LEAFLET

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS AND TENDON RUPTURE (inflammation or rupture in tissue that connects a bone to a muscle), PERIPHERAL NEUROPATHY (Disorders related to any cause in the nerves far from the center - loss of sense) EFFECTS ON CENTRAL NERVOUS SYSTEM AND EXACERBATION OF MYASTENIA GRAVIS (a type of muscle weakness)

- Antibiotics called fluoroquinolone, including levofloxacin, which is one of the active ingredients of BERAXİN, can cause irreversible undesirable effects that can lead to disabilities, as follows:
  - Inflammation in the tissues that connect the muscles to the bones (tendinitis; symptoms may be severe pain, swelling and redness in the joints) and rupture in the tissues (tendon) that connect the muscles to the bones (symptoms may be severe pain in the muscles, sudden and rapid bruising, weakness, inability to move)
  - Disorders related to any cause in the nerves far from the center - loss of sense (peripheral neuropathy; Symptoms may be pain in the nerves, tenderness, numbness with tingling in the feet and hands, weakness in the muscles, tremors in the hands.)
  - Effects on central nervous system (symptoms may be hallucination, anxiety, depression, suicidal tendency, insomnia, severe headache and confusion)

If any of these undesirable effects occur during BERAXİN use, stop taking BERAXİN immediately, avoid the use of fluoroquinolone antibiotics (e.g. levofloxacin, moxifloxacin, ciprofloxacin) and talk to your doctor or pharmacist.

-Antibiotics called fluoroquinolone, including levofloxacin, which is one of the active ingredients of BERAXİN, can exacerbate muscle weakness in patients with myasthenia gravis (a type of muscle weakness disease). If you have a known muscle weakness disease, avoid the use of fluoroquinolone antibiotics (e.g. levofloxacin, moxifloxacin, ciprofloxacin) and talk to your doctor or pharmacist before BERAXİN use.

-Since it is known that fluoroquinolone drugs, including levofloxacin, which is one of the active ingredients of BERAXİN, is associated with serious adverse reactions, it can be used in the following indications if there are no other alternatives.
  - Sudden onset inflammation of the air-filled cavities within the facial bones caused by bacteria (Acute bacterial sinusitis)
  - Uncomplicated (simple) urinary tract infection
  - Acute bacterial exacerbation of chronic bronchitis (sudden worsening of bronchitis, a type of lung inflammation that has been going on for a long time, due to bacteria)

BERAXİN 750 mg film coated tablets
For oral use.

- ***Active substance(s):*** Each film-coated tablet contains 768.69 mg of levofloxacin hemihydrate equivalent to 750 mg of levofloxacin.
- ***Excipient(s):*** Microcrystalline cellulose PH 102, hydroxypropyl methyl cellulose, crospovidone, sodium stearyl fumarate and as film coating agent (Opadry II Yellow): talc, polyvinyl alcohol, polyethylene glycol, ponso 4R lacquer (E124), titanium dioxide (E171), quinoline yellow aluminum lacquer (E104).

Read this PACKAGE LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

1. What BERAXİN is and what it is used for?

It should not be used in acute bacterial sinusitis (inflammation of the air-filled cavities called sinuses within the facial bones), acute bacterial exacerbation of chronic bronchitis (sudden worsening of bronchitis, a type of lung inflammation that has been going on for a long time, due to bacteria) and uncomplicated (simple) urinary tract infection due to the risk of serious side effects, if there are alternative treatment options. In addition, it is necessary to prove sensitivity with antibiogram in urinary tract infections.

- BERAXİN is a yellow film-coated oblong (rectangular) tablet containing levofloxacin, a synthetic, fluoroquinolone-derived broad-spectrum antibacterial, as an active ingredient..

- BERAXİN is marketed in PVC-PE-PVDC / Aluminum blister packaging with 7 film tablets containing 768.69 mg levofloxacin hemihydrate, equivalent to 750 mg of levofloxacin.

- BERAXİN is used in the treatment of lung, sinus, urinary tract, skin and soft tissue infections.

- BERAXİN is used in the treatment of the following infections:
- Community-acquired pneumonia
- Hospital-acquired (nosocomial) pneumonia

- Sudden (acute) exacerbation of long-standing bronchitis disease (long-standing respiratory infections that cause breathing difficulties)
- Sudden onset (acute) inflammation of the air-filled cavities within the facial bones caused by bacteria (sinusitis) (acute bacterial sinusitis)
- Uncomplicated and complicated (severe) urinary tract (urinary system) infections
- Prolonged prostatitis (chronic bacterial prostatitis)
- Kidney infection (acute pyelonephritis)
- Uncomplicated and complicated (severe) skin and soft tissue infections (skin or subcutaneous infections)
- In case of possible ingestion of the anthrax germ through the respiratory tract (inhaled anthrax after exposure)

2. What you need to know before you use BERAXİN?

Do not use BERAXİN

- If you are allergic to levofloxacin or any of the other ingredients of this medicine, or to other fluoroquinolone antibiotics (moxifloxacin, ciprofloxacin, gemifloxacin, ofloxacin)
- If you have experienced tendon (bond between muscle and joint) problem due to the use of fluoroquinolone group antibiotics
- If you have had epileptic seizures
- Especially in elderly patients or patients taking corticosteroids (cortisone and similar medicines)
- If tendon inflammation and pain occur during BERAXİN treatment
- If severe, persistent and / or bloody diarrhea occurs during or immediately after BERAXİN treatment
- If you are pregnant, think you are pregnant or are planning to become pregnant
- If you are breastfeeding, do not use this medicine.
- This medicine is for adults only. It should not be given to children under 18 years of age.

Warnings and precautions

- If you have a known heart disease or family history of cardiac conduction disorder (QT prolongation)
- If you have diabetes (diabetes), if you are taking sugar-lowering medication (antidiabetic)
- If you have a nervous system disease or mental illness
- If you have had a stroke or other brain disease that caused brain damage
- If you are 65 years old or over
- If you have glucose-6-phosphate dehydrogenase enzyme deficiency disease
- If you have kidney problems (Your doctor may decrease your drug dose).
- If you have liver problems
- If you are directly exposed to sunlight and artificial ultraviolet lamps such as tanning beds
- If you have had a seizure (referral) before
- If you are taking medications containing corticosteroids
- In patients with a history of myasthenia gravis (impaired nerve-muscle conduction and thus abnormal fatigue seen in patients with myasthenia), a type of muscle weakness disease.
- Potentially irreversible serious adverse reactions that can cause disability, including tendinitis (swelling and pain around the joint) and tendon rupture, peripheral neuropathy (pain, numbness, needling at the ends of the body and muscle weakness) and effects on the central nervous system.

  Fluoroquinolones, including BERAXİN, have been associated with potentially irreversible serious adverse reactions that can cause disability. Common adverse effects include: musculoskeletal and peripheral nervous system effects (tendinitis (swelling and pain around the joint), tendon (ligament that connects the muscles to the bones) rupture (swelling or inflammation in the tendons, tingling or numbness, numbness in the arms and legs, muscle pain, muscle weakness, joint pain, joints swelling), arthralgia (joint pain), myalgia (muscle rheumatism, muscle pain), peripheral neuropathy (pain, numbness, needling in the ends of the

body and muscle weakness) and central nervous system effects (hallucination, anxiety, depression, suicidal tendency, insomnia, severe headache and confusion) (See Section 4. Possible side effects?).
These reactions can occur within hours or weeks after starting BERAXİN. Patients of all age groups or patients without pre-existing risk factors experienced these undesirable effects.
Use of BERAXİN should be discontinued immediately if the first signs or symptoms of any serious adverse side effects occur. In addition, the use of fluoroquinolone antibiotics, including BERAXİN, should be avoided in patients experiencing any of these serious adverse effects associated with fluoroquinolone antibiotics.

Use BERAXİN carefully.

If you are exposed to sunlight while using BERAXİN, your skin may be sensitive and sunburned. Therefore, use high factor sun creams. Wear a hat and clothes which cover your arms and legs. Avoid sun beds.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

BERAXİN with food and drink
Take BERAXİN with sufficient amount of liquid without chewing. You can take the tablets during or between meals.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
There are no adequate and well-controlled studies in pregnant women, therefore BERAXİN should not be used during pregnancy.
Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding
Consult your doctor or pharmacist before taking this medicine.
BERAXİN should not be used during breastfeeding.

Driving and using machines
BERAXİN can cause side effects such as dizziness, drowsiness and sleepiness. Some of these side effects can impair the patient's ability to concentrate and react. Therefore, caution should be exercised when driving and using machines.

Important information about some of the ingredients of BERAXİN
The excipient ponso 4R lacquer (E124) used as a colorant in BERAXİN can cause allergic reactions in sensitive individuals.

Other medicines and BERAXİN
- When BERAXİN is taken together with iron salts (used for anemia), zinc-containing multivitamins, magnesium or aluminum-containing antacids used for heartburn and sucralfate used in the treatment of stomach ulcers, take BERAXİN at least two hours before or after the administration of these medicines, as these significantly reduce the absorption of BERAXİN.
- When administered together with calcium carbonate, there is no significant change in its absorption, distribution or excretion from the body (pharmacokinetics).
- When used with quinolone group antibiotics, an increase in theophylline (used in dyspnea) levels is detected, so when used with BERAXİN, theophylline levels should be monitored. If theophylline is used together with BERAXİN, the risk of epileptic seizures may increase.

- During the concomitant use of BERAXİN and warfarin, which is a blood thinner (vitamin K antagonist), the duration of your blood clotting (prothrombin time) and bleeding symptoms should be followed.
- If non-steroidal anti-inflammatory drugs (aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin) used for rheumatic pain and rheumatic inflammation are taken together with BERAXİN, the risk of epileptic seizures may increase.
- Increase or decrease in blood sugar (hyperglycemia-hypoglycemia) has been reported during the concomitant use of BERAXİN and blood sugar lowering (antidiabetic) drugs. Therefore, blood sugar levels should be monitored when used together.
- Probenecid used in gout and cimetidine used against heartburn can reduce the excretion of BERAXİN from the kidneys.
- BERAXİN can prolong the effect of the drug called cyclosporine used in organ transplants.
- In case of use with BERAXİN, antiarrhythmic drugs (quinidine and amiodarone; used in the treatment of abnormal heart rhythm), drugs used in the treatment of depression (tricyclic antidepressants; amitriptyline and imipramine) and some drugs used in the treatment of bacterial infections (macrolide antibiotics; erythromycin, azithromycin and clarithromycin) may affect your heart rhythm.
- When BERAXİN is used with corticosteroids, the structures called tendons that connect muscles to bones are more likely to become inflamed.
- The use of strong painkillers called opiates together with BERAXİN may cause "false positive" results in urine tests. Therefore, if you use this type of medication, tell your doctor.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use BERAXİN?

- **Instructions for use and dosage/frequency of administration:**

Your doctor will determine the dose you will take and the duration of treatment with BERAXİN.
BERAXİN is used once a day.
The dosage depends on the type and severity of the infection, as well as the susceptibility of the bacteria that is the cause of the infection.
The duration of treatment depends on the course of your disease.
As with all antibiotic treatments in general, BERAXİN use should be continued for at least 48-72 hours after the patient's fever has go down and evidence has been provided that the infection has been eliminated.

- **Route of administration and method:**

Use BERAXİN orally. It should be taken with a sufficient amount of liquid without chewing.
The tablets can be taken during or between meals.
Take the tablets at the same time of the day.

- **Different age groups:**

  Use in children:
  It should not be used in children under 18 years of age.

  Use in elderly:
  Dose adjustment is not required in elderly patients if renal function is sufficient.

- **Special cases of use:**

  Renal failure:
  The dose of BERAXİN should be adjusted in renal failure. In the use of BERAXİN, the dose will be adjusted by your doctor to prevent accumulation. Hemodialysis and continuous ambulatory peritoneal dialysis, which are methods used to remove waste materials from the

blood in patients with renal failure, have no effect on the elimination of BERAXİN from the body.

Hepatic failure:
There is no need for dose adjustment in hepatic failure.

If you have impression that the effect of BERAXİN is very strong or weak, tell a doctor or pharmacist.

If you use more BERAXİN than you should:
If you take more BERAXİN than you should, tell your doctor or pharmacist.
In overdose, central nervous system symptoms such as confusion, dizziness, loss of consciousness and epilepsy, digestive system reactions such as nausea, heartburn, and cardiac symptoms such as heart rhythm disturbance may occur.
In case of overdose, consult your doctor or a hospital immediately.

If you forget to use BERAXİN:
If you forget to take a dose, do not worry. If the time for your next dose is not close, take one as soon as you remember. Take your next dose at your usual time.
Do not take a double dose to make up for a forgotten dose.

If you stop using BERAXİN:
None.
However, even if you feel better, use your medication until your treatment period is over.

4. Possible side effects?
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects were listed by frequency as following:
Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data.

If you notice any of the followings stop taking BERAXİN and immediately inform your doctor or go to the nearest emergency department:

Rare
- Tendinitis

Very rare
- A sudden onset and life-threatening allergic reaction (anaphylactic shock)
- Tendon rupture (inflammation or rupture in the tissues that connect the muscles to the bones)
- Muscle weakness
- Peripheral neuropathy (disorder related to any cause in the nerves far from the center - loss of sense)

Not known

- If you have an allergic reaction (hypersensitivity), symptoms may include: redness, swallowing or breathing problems, swelling of lips, face, throat, or tongue

These are all very serious side effects.
If you have one of these, you may need emergency medical intervention or hospitalization.

If you notice any of the followings immediately inform your doctor or go to the nearest emergency department:

Rare

- Watery diarrhea combined with possibly stomach cramps and high fever which can also be bloody. These may be symptoms of serious bowel problem.
- Convulsions

Not known

- Severe skin rash, including blistering or peeling of the skin around the eyes, lips, mouth, nose and genitals
- Loss of appetite, yellowing of the white part of the eye and skin, darkening of the urine color, itching, tenderness in the abdomen. These can be symptoms of liver problems.

These are all serious side effects. You may need an emergency medical intervention.

If you experience any one of the followings tell your doctor:

Common

- Feeling sick (nausea) and diarrhea
- Increase in the level of some liver enzymes in your blood

Uncommon

- Itching and redness of the skin
- Loss of appetite, stomach upset or indigestion (dyspepsia), vomiting or abdominal pain, bloating or constipation
- Headache, drowsiness, dizziness, insomnia or irritability
- Abnormal results in blood tests due to liver or kidney problems
- Changes in the number of white blood cells seen in the results of some blood tests
- Weakness
- Changes in the number of other bacteria or fungi that may need to be treated

Rare

- Tingling sensation (paresthesia) or tremors in your hands and feet
- Anxiety, distress, depression, restlessness or confusion
- Palpitations or low blood pressure
- Joint or muscle pain
- Bleeding and bruising can easily occur due to the low number of cells (thrombocytes) that cause clotting in the blood
- Decrease in white blood cell count
- Difficulty breathing or wheezing (bronchospasm)
- Shortness of breath (dyspnoea)

- Severe itching or skin rash

Very rare
- Increased sensitivity of the skin to sun and ultraviolet light
- Low blood sugar (hypoglycaemia). This is important for people with diabetes.
- Vision and hearing disorders or taste and smell disorders
- Psychotic reactions with self-destructive behavior including seeing or hearing things that are not real (hallucinations), suicidal thoughts and suicide attempt
- Circulatory disorder (anaphylactic-like reactions)
- Rupture in the structure called tendon that connect the muscles to the bones (this undesirable effect can occur within the first 48 hours of treatment and on both sides), muscle weakness (This is important in people with myasthenia gravis (nerve-muscle conduction disorder), a type of muscle weakness disease).
- Liver inflammation, kidney disorders and renal failure due to interstitial nephritis, an allergic kidney reaction.
- Fever, sore throat and a prolonged general feeling of being unwell. This may be due to a decrease in the number of white blood cells.
- Fever and allergic lung reactions
- Aggravation of myasthenia gravis, a disease with excessive muscle weakness

Not known
- Decrease in the number of red blood cells (anemia). This condition can make the skin pale or yellow due to damage of the red blood cells and a decrease in the number of all types of blood cells.
- Exaggerated immune response (hypersensitivity)
- Excessive sweating
- Pain in the back, chest, arms and legs
- Difficulty moving and walking
- Attacks in patients with porphyria, a very rare metabolic disease
- Blood vessel inflammation due to an allergic reaction

These are the mild side effects of BERAXİN.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store BERAXİN?
Keep in the original package and out of the reach and sight of children.

Store in room temperature under 25°C.

Use in accordance with expiry date.

Do not use this medicine after the expiry date which is stated on the packaging.

If you notice any signs of deterioration in the tablets, contact your pharmacist to tell you what to do.

Do not use this medicine if you notice any damage to the product and/or package.

Marketing Authorization Holder:
Berko İlaç ve Kimya Sanayi A.Ş.
Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey
+90 216 456 65 70 (Pbx)
+90 216 456 65 79 (Fax)
info@berko.com.tr

Manufacturer:
Berko İlaç ve Kimya Sanayi A.Ş.
Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey
+90 216 592 33 00 (Pbx)
+90 216 592 00 62 (Fax)

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