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.

-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)
- 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 500 mg film coated tablets
For oral use.

- ***Active substance(s):*** Each film coated tablet contains 512.46 mg levofloxacin hemihydrate equivalent to 500 mg levofloxacin.

- ***Excipient(s):*** Microcrystalline cellulose PH 102, hydroxypropyl methyl cellulose, crospovidone, sodium stearyl fumarate and film coating agent (Opadry II Yellow): talc, polyvinyl alcohol, polyethylene glycol, ponso 4R lacquer (E124), titanium dioxide (E171), quinoline yellow aluminum lacquer (E104).

Read all of this LEAFLET carefully before you start taking 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher** or **lower** doses other than the recommended to 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) and 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) due to the risk of serious side effects, if there are alternative treatment options.

- BERAXİN is used orally. The box contains 7 yellow colored oblong (rectangular) film-coated tablets containing 500 mg of levofloxacin, with a notch on one face. The tablet is notched to facilitate dose adjustment.
- BERAXİN is an effective antibiotic against bacteria. It belongs to the group of antibiotics called fluoroquinolones. It prevents the growth and reproduction of bacteria and ensures the elimination of bacteria.
- It is used in the treatment of infections caused by bacteria sensitive to levofloxacin, the active ingredient of BERAXİN.
- Your doctor may have prescribed BERAXİN because you have one of the following conditions::
  - Sudden onset (acute) inflammation of the air-filled cavities within the facial bones caused by bacteria (sinusitis)
  - Sudden (acute) exacerbation of long-standing bronchitis disease (chronic bronchial inflammation)

- Community-acquired pneumonia (pneumonia)
- Complicated kidney and urinary tract infections, including inflammation of the urinary tract and kidney (pyelonephritis)
- Prostate inflammation
- Skin and soft tissue infections: abscess (pus sac); cellulite; hair root inflammation (furuncle); infectious and superficial microbial infection (impetigo) of the skin; purulent skin infection (pyoderma); uncomplicated skin and underneath the skin infections caused by wound infections
- Exposure to airborne anthrax microbe

2. What you need to know before you take BERAXİN
DO NOT take BERAXİN:

- If you are allergic to levofloxacin or any of the other ingredients of this medicine, or to other fluoroquinolone antibiotics (moxifloxacin, ciprofloxacin, ofloxacin).
  Signs of an allergic reaction include: itching, swallowing or breathing problems, swelling of the lips, face, throat, or tongue
- If you have epilepsy disease
- If you have experienced tendon (bond between muscle and joint) problem (tendonitis) due to the use of quinolone group antibiotics.
- If you are pregnant
- If you are breastfeeding
- In children and growing teenagers.

It should not be used in children, growing teenagers, pregnant and lactating women as these could harm the cartilage of growing bones.

Warnings and precautions
- If you have a very severe lung infection or a serious hospital infection (using another antibiotic may be more appropriate)
- If you have a condition that affects your central nervous system and you have had involuntary contraction related to it
- If you have brain damage due to a stroke or other brain injury
- In cases of bowel inflammation with bloody, watery diarrhea due to long-term antibiotic use: If severe, persistent and / or bloody diarrhea occurs during or after BERAXİN treatment, BERAXİN treatment should be terminated immediately and appropriate supportive and / or specific treatment should be started. Inform your doctor immediately. Your doctor will determine the appropriate treatment for you.
- The risk of tendon rupture increases in the elderly and patients who use corticosteroids, if pain, redness, restricted mobility arises, which may suggest an inflammation or rupture in the tendons. In this case, your doctor may want to follow you closely.
- If you have kidney failure, your doctor will make a special dose adjustment for you.
- Photosensitivity has been reported rarely in patients using BERAXİN. Do not stay in strong sunlight or do not be exposed to artificial ultraviolet rays such as solarium during the use of BERAXİN and after treatment for 48 hours.
- In case of a second infection in the body, which is weakened by any infection (superinfection): As with other antibiotics, it may cause excessive growth of non-resistant organisms as a result of its long-term use. Your doctor may want to follow you closely to prevent this. If superinfection occurs, your doctor will apply appropriate treatment methods.
- If you have prolonged QT interval which is a condition that can cause serious arrhythmias and sudden death: Prolongation of the QT interval has been reported very rarely in patients who

received fluoroquinolone antibiotics, including levofloxacin. Caution should be exercised in the following risk groups:
  - if you are older (over 65) or women
  - if you have had liver problems
  - if you are taking corticosteroids
  - if you have an uncorrected electrolyte imbalance (e.g. low levels of potassium and magnesium in the blood)
  - if you have congenital QT syndrome (a condition that can lead to serious arrhythmias and sudden death)
  - if you have heart disease (heart failure, a history of heart attack, slow heartbeat)
  - Concomitant use of drugs known to prolong the QT interval (e.g. Class IA and III rhythm-regulating drugs, some depression medicines, macrolide group antibiotics and antipsychotics for the treatment of mental disorders)
- If you have a congenital deficiency of an enzyme called glucose-6-phosphate dehydrogenase
- Decreased blood sugar level (hypoglycemia) and increased blood sugar level (hyperglycemia): If you have diabetes (diabetes) and you are taking insulin or oral medications for this, your blood sugar may decrease or coma associated with it may occur or your blood sugar may rise (your doctor may ask you to check your blood sugar regularly)
- If you have any cause-related disorder (peripheral neuropathy) in your nerves
- Exacerbation of myasthenia gravis, a type of muscle weakness disease: Fluoroquinolones have an activity that inhibits muscle-nerve conduction and may exacerbate muscle weakness in patients with myasthenia gravis. In patients with myasthenia gravis using fluoroquinolone, serious post-marketing side effects involving respiratory failure requiring respiratory equipment support and death have been associated with fluoroquinolone. Fluoroquinolone should be avoided in patients with a history of myasthenia gravis.
- Hypersensitivity reactions: Serious hypersensitivity reactions (swelling of the face and throat as a result of allergies), which can rarely be lethal after the first dose, may occur. You should stop treatment and consult your doctor for urgent action.
- Severe diseases with water-filled blisters on the skin: BERAXİN can cause severe skin reactions such as Stevens-Johnson syndrome (inflammation with swelling and redness on the skin and around the eyes) and toxic epidermal necrolysis (a serious disease with fluid-filled blisters on the skin). In this case, contact your doctor immediately before continuing treatment.
- Suicidal thoughts and dangerous behavior can be observed very rarely following a single dose of levofloxacin. In this case, your doctor may terminate your treatment and determine the appropriate treatment method for you.
- Take BERAXİN carefully if you have a psychological condition or a history of psychiatric illness.
- If you experience loss of appetite, jaundice, dark urine, itching, or abdominal tenderness during your treatment, contact your doctor immediately. Your doctor may terminate the treatment and determine the appropriate treatment for you.
- 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.

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

Taking BERAXİN with food and drink
The absorption of BERAXİN is not affected by food, you can take the tablet in amount recommended by your doctor before or after meals.
If you need to use magnesium or aluminum or iron or zinc-containing medicines, medicines called antacids that neutralize stomach acid, or sucralfate or didanosine (didanosine formulations with buffers containing magnesium or aluminum only) for gastric ulcer or reflux disease, take BERAXİN at least two hours before or after the administration of these medicines, as these may affect the absorption of BERAXİN.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
There is insufficient information on the use of levofloxacin in pregnant women.
The potential risk for humans is unknown. BERAXİN should not be used during pregnancy, since human data are not sufficient and experimental studies with fluoroquinolones show the risk of damaging cartilage that carries weight in growing organisms.
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.
There is insufficient / limited information regarding the excretion of levofloxacin in human or animal milk. It cannot be excluded that there is a risk for the breast-fed child due to the physicochemical and available pharmacodynamic / toxicological information for the excretion of levofloxacin in milk. BERAXİN should not be used during breast-feeding, since human data are not sufficient and experimental studies with fluoroquinolones show the risk of damaging cartilage that carries weight in growing organisms.

Driving and using machines
The use of BERAXİN may cause some undesirable side effects such as drowsiness / dizziness, vision disorders, and sleepiness, which can impair the patient's ability to concentrate and react. In situations that require special attention, such as driving and using machines, a reduction in these abilities may pose a risk.
If you experience such side effects while using BERAXİN, do not drive or use machines.

Important information about some of the excipients 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

- Theophylline, a drug that expands the bronchi and facilitates breathing: When used with BERAXİN, the threshold of contraction seizures in the brain is reduced.
- When using non-steroidal anti-inflammatory drugs such as fenbufen, ketoprofen, ibuprofen, aspirin and indomethacin with BERAXİN, the threshold of contraction seizures in the brain is reduced.
- Probenecid used for gout or cimetidine used for stomach ulcer reduce the excretion of BERAXİN from the body.
- Sucralfate (used to treat stomach ulcers) reduces the absorption of BERAXİN.
- Cyclosporine, a drug that suppresses the immune system (half-life is extended)
- The effect of vitamin K antagonists (eg warfarin) used to prevent blood clotting may increase, the risk of bleeding may occur. Your doctor may ask you for blood clotting tests.
- Drugs known to prolong the QT interval in the heart (may cause severe arrhythmia in the heart.)
  - Class IA antiarrhythmics (quinidine) and Class III antiarrhythmics (amiodarone) that prevent rhythm disturbances in the heart
  - Some depression medications (tricyclic antidepressants) (eg amitriptyline, imipramine)
  - Macrolides, an antibiotic group (erythromycin, azithromycin, clarithromycin)
  - Antipsychotics used in the treatment of some mental illnesses
  - Corticosteroids (used to treat asthma and inflammation.)
- Urine tests may show "false positive" results for strong painkillers called opiates while using this medicine.

Other drugs: Digoxin used to treat heart failure, glibenclamide used to lower blood sugar, and ranitidine used to treat stomach ulcers, are not expected to alter the effect of BERAXİN.

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 the BERAXİN?

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

Your doctor will tell you how and in what dosage you should use your medicine. BERAXİN is used in adults.

BERAXİN is used once or twice 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.

It is recommended to use BERAXİN in the following doses:

Disease	**Daily dosage** *(based on the severity of the infection)*	**Treatment duration**
Acute sinusitis (inflammation of the air-filled cavities within the facial bones)	500 mg once daily	10-14 days
Acute exacerbation of chronic bronchitis (bronchial inflammation)	250 - 500 mg once daily	7-10 days
Community-acquired pneumonia (pneumonia)	500 mg once daily or 2 times a day	7-14 days

Urinary tract and kidney inflammation (Pyelonephritis)	500 mg once daily	7-10 days
Complicated urinary tract infections	500 mg once daily	7-14 days
Skin and soft tissue infections	250 mg once daily or 500 mg single dose / twice daily	7-14 days
Prolonged prostate inflammation (Chronic bacterial prostatitis)	500 mg once daily	28 days
Exposure to airborne anthrax microbe	500 mg once daily	8 weeks

The duration of treatment depends on the course of your disease (see table above). 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:**

BERAXİN is used orally. Swallow the tablet with sufficient amount of liquid without crushing the tablet. You can divide it by the notch line to follow the dosage. You can take the tablets with or between meals.
Take BERAXİN at least two hours before or after administration of iron salts, antacids that reduce stomach acid, or sucralfate used to treat stomach ulcers, as absorption may decrease.

Protection from sunlight
Do not be exposed to direct sunlight while using this medicine. Your skin will become much more sensitive to the sun and may burn, tingle or severely blister. Therefore, use high factor sun creams. Wear a hat and clothes which cover your arms and legs. Avoid sun beds.

- **Different age groups:**
  Use in children:
  BERAXİN is not used in children and growing teenagers.

  Use in elderly:
  In the elderly, if there is no impairment in kidney function, no dosage adjustment is required.

- **Special cases of use:**
  Kidney failure:
  If you have impaired kidney function, your doctor will reduce the dose of BERAXİN and monitor you more closely.
  Dosage (based on the severity of the infection) will be determined by your doctor in patients with creatinine clearance ≤ 50 ml / min.

  Liver failure:
  In the case of impaired liver function, no adjustment to the dose of BERAXİN is required.
  Your doctor will tell you how long your treatment will last with BERAXİN. Do not stop your treatment without consulting your doctor.

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

If you take more BERAXİN than you should:
If you take more BERAXİN than you should, tell your doctor or pharmacist.
Overdose symptoms; signs related to the central nervous system, such as confusion, drowsiness, and involuntary contractions in muscles, rhythm disturbance in the electrocardiogram (ECG) (prolonged QT interval) and nausea.

If you forget to take BERAXİN:
If you forget to take a dose, take it as soon as you remember.
Do not take a double dose to make up for a forgotten dose.

If you stop taking BERAXİN:
Do not stop your BERAXİN treatment without consulting your doctor, the infection may return and the bacteria may become resistant to the medicine.

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 {name of the medicine} and immediately inform your doctor or go to the nearest emergency department:

Rare
- Widespread itching and rash on the skin, swelling of the lips, face, throat and tongue, difficulty breathing and swallowing (hypersensitivity, angioedema)
- Tendinitis
- Muscle weakness

Not known
- A sudden onset and life-threatening allergic reaction (anaphylactic shock)
- Stevens-Johnson syndrome, a serious disease with skin peeling, swelling, blisters on the skin, mouth, eyes, around the genitals and fever; erythema multiforme, an inflammatory disease with blood blister, swelling and redness on the skin and around the eyes; toxic epidermal necrolysis, a serious disease with the skin with fluid-filled blisters
- Tendon rupture (inflammation or rupture in the tissues that connect the muscles to the bones)
- Peripheral neuropathy (disorder related to any cause in the nerves far from the center - loss of sense)

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

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

Rare
- Involuntary contractions in the muscles (convulsions)

Not known
- 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, which can sometimes be fatal.
- Abnormal heart rhythm, palpitations
- Severe abdominal pain in the form of cramps and high fever combined with severe, persistent, bloody diarrhea (these may be symptoms of serious bowel problem)
- Joint ligaments and muscle rupture, joint inflammation

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
• Nausea, vomiting, diarrhea
• Increase in the level of some liver enzymes in your blood
• Headache, drowsiness
• Insomnia

Uncommon
- Fungal infections, resistance development in other microbes
- Itching and skin rash, hives, excessive sweating
- Abdominal pain, indigestion, loss of appetite, flatulence, constipation
- Dizziness (vertigo)
- Anxiety, confusion, irritability
- Sleepiness, tremor, impaired sense of taste
- Shortness of breath (dyspnea)
- Joint or muscle pain
- Blood tests may show unusual results due to liver or kidney problems (bilirubin increased, creatinine increased)
- Decreased white blood cell count (leukopenia)
- Weakness

Rare
- Lowering of your blood sugar levels. This is important for diabetics and can cause coma.
- Mental disorder, restlessness, depression, which may be accompanied by visual and auditory hallucinations and excessive suspicion (paranoia)
- Abnormal dreams, nightmares
- Visual impairments including blurred vision
- Tinnitus
- Muscle weakness. This is important for patients with myasthenia gravis, a rare disease related to the nervous system.
- Low blood pressure

- Fast heartbeat, palpitations
- Bleeding and bruising can easily occur due to the low number of cells (thrombocytes) that cause clotting in the blood (thrombocytopenia).
- Decrease in white blood cell count (neutropenia)
- Fever
- Altered kidney function and kidney failure due to allergic kidney reactions called interstitial nephritis

Very rare
- Attacks in patients with porphyria, a rare metabolic disease

Not known
- Coma due to low blood sugar
- High blood sugar
- Self-destructive behavior, including suicidal thoughts and suicide attempt
- Loss of taste
- Disturbances of smell, including loss of smell
- Fainting (syncope), benign intracranial hypertension
- Impairment or loss of hearing
- Temporary loss of vision
- Increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)
- Lowering in the number of all types of blood cells (pancytopenia) or red blood cells (anemia). The skin may be pale and yellow due to damage of the red blood cells and a decrease in the number of all types of blood cells. Fever, sore throat and a general feeling of being unwell may occur.
- Inflammation in the mouth (stomatitis)
- Exaggerated immune response (hypersensitivity).
- Problems moving and walking (dyskinesia, extrapyramidal disorder)
- Allergic-induced pneumonia
- Inflammation of the blood vessels caused by an allergic reaction
- Pancreatic inflammation (pancreatitis)
- Pain (back, chest, extremities)

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

5. How to store BERAXİN?
Keep this medicine out of sight and reach of children and store in the original package.
Store at room temperature below 25°C.

Use in accordance with expiry date.
Do not use this medicine after the expiry date which is stated on the packaging.

Do not use this medicine if you notice any defects in the product and / or packaging.

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