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Adiflox 500 mg film-coated tablets

(Levofloxacin)

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 your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What is Adiflox and what it is used for
2. Before you take Adiflox
3. How to take Adiflox
4. Possible side effects
5. How to store Adiflox
6. Content of the pack and other information

1. What Adiflox is and what it is used for

The name of your medicine is Adiflox. It contains levofloxacin, broad-spectrum quinolone antibiotic. It has antibacterial effect by stopping bacterial growth of different bacteria species causing infections in your body.

Your doctor has prescribed you levofloxacin for treatment of some of the following bacterial infections:

- Infections of sinuses
- Infections of lungs, respiratory tracts or pneumonia
- Infections of urinary tract, including kidneys or bladder
- Infections of prostate gland
- Skin and soft-tissue infections.

2. What you need to know before you take Adiflox tablets

Do not take Adiflox and tell your doctor:

If you are allergic (hypersensitive) to Levofloxacin or any of the ingredients of this medicine (listed in section 6), or if you allergic to any other quinolone antibiotic (ofloxacin, ciprofloxacin);

- Signs of an allergic reaction can be: a rash, swallowing or breathing problems, swelling of your lips, throat or tongue
- suffer epilepsy;
- have had tendon problems and were treated with quinolone antibiotic;
- you are pregnant, might become pregnant or planning pregnancy;
- are breast – feeding, this medicine could harm your baby;
- this medicine is prescribed only to adults, it should not be given to children and youths in the growing period (under 18 years), since there is a risk of joint harming;

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Adiflox.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking your Adiflox if:

- you are 60 years of age or older
- you are using corticosteroids (see section Other medicines and Adiflox)
- you have ever had a fit (seizure)
- you have had damage to your brain (such as stroke or severe brain injury)
- have had or have kidney problems
- you have something known as “glucose-6-phosphate dehydrogenase deficiency”-you are more likely to have serious problems with your blood when taking this medicine
- you have ever had mental health problems
- you have ever had heart problems: caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called “bradycardia”), have a weak heart (heart failure), have a history of heart attack, you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section “Other medicines and Adiflox)
- You are diabetic
- You have ever had liver problems
- You have myasthenia gravis

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Adiflox.

Other medicines and Adiflox

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is because Adiflox can affect the action of other medicines, and some medicines can affect the action of Adiflox.

In particular, tell your doctor if you are taking any of the following medicines

Corticosteroids – you may be more likely to have inflammation and/or breakage of your tendons;

Theophylline - used for breathing problems. You are more likely to have a fit (seizure) if taken Adiflox

Warfarin (Vitamin K antagonists) – used to thin the blood. You may be more likely to have a bleed. Your doctor will take regular specific blood tests.

Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain

and inflammation such as aspirin, fenbufen, ibuprofen, ketoprofen, indomethacin etc. You are more likely to have a fit (seizure) if taken with Adiflox;

Cyclosporin – immunosuppression medicine product used after organ transplants. You may be more likely to get the side effects of Cyclosporin and levofloxacin may prolong the action of cyclosporine.

Probenecid (used for gout), and **cimetidine** (used for ulcers and heartburn) decrease the kidneys capability for elimination of Adiflox, because of which special care should be taken.

Medicines, used for treatment of heart function and abnormal heart rhythm – (antiarrhythmic such as quinidine, hydroquinidine, disopyramide, sotalol, dofetilide, ibutilide and amiodarone).

Antidepressants (tricyclic antidepressants – amitriptyline and imipramine).

Antibacterial infections – macrolide antibiotics (erythromycin, azithromycin, clarithromycin). See section: “Take special care using Adiflox”.

Do not take Adiflox at the same time as the following medicines:

Medicines containing iron (against anemia), food supplements containing zinc, magnesium or aluminium-containing antacids (for acid or heartburn), didanosine, or sucralfate (for stomach ulcers).

Urine tests for opiates

Urine tests may show “false-positive” results for strong painkillers called “opiates” in people taking Adiflox with analgesic medicine. If your doctor is due to take a urine test, tell him you are taking Adiflox.

Adiflox with foods, drinks and alcohol

Adiflox could be administered during or between meals. Do not use alcohol during Adiflox treatment.

Pregnancy, breast – feeding and fertility

Ask your doctor or pharmacist before taking any medicine.

Do not take Adiflox if you are pregnant or trying to become pregnant, or think you might be pregnant. Do not take Adiflox if you are breast-feeding or planning to breast-feed.

Driving and using machines

You may get side effects after taking Adiflox, including feeling dizzy, sleepy, a spinning feeling (vertigo), and changes to your eyesight, etc. These side effects can affect you being able to concentrate and your reaction speed. If this happens in Adiflox administration, do not drive or carry out any work that requires a high level of attention.

3. How to take Adiflox

Always take Adiflox exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Film – coated tablets Adiflox should be swallowed whole with sufficiency of liquid. Prescribed dose should be taken in regular intervals of 12 or 24 hours. Tablets could be taken during or between meals.

Protect yourself from direct sunlight

Keep out of direct sunlight while taking this medicine and for 2 days after you stop taking it and take following precautions to protect yourself – wear a hat, use sun creams, as increasing the risk for redness of your skin and to receive rash.

If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate

Do not take these medicines at the same time as Adiflox. Take Adiflox at least 2 hours before or after taking these medicines, so you will avoid the possibility for decreasing the levofloxacin action.

How much Adiflox to take

- Your doctor will decide on how many Adiflox tablets you should take
- The dose will depend on the type of infection you have and where the infection is in your body
- The length of your treatment will depend on how serious your infection is
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor

Adults and the elderly

Sinuses infection – 500 mg, once a day

Lungs infection, in people with long-term breathing problems – 500 mg, once a day

Pneumonia - 500 mg, once or twice a day

Infection of urinary tract, including kidneys and bladder – 250 mg or 500 mg, once a day

Prostate gland infection - 500 mg, once a day

Infection of skin and soft tissues - 500 mg, once or twice a day

Adults and elderly with kidney problems

As the Adiflox is excreting mainly through the kidneys, your doctor may need to give you a lower dose. Follow the instructions of your doctor.

Children and teenagers

Adiflox must not be given to children or teenagers

If you take more Adiflox than you should

If you accidentally take more tablets than you should, tell a doctor or get other medical advice straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling confused, dizzy, and less conscious, having tremor and heart problems – leading to uneven heart beats as well as feeling sick (nausea) or having stomach burning.

If you forget to take Adiflox tablets

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not double-up the next dose to make up for the missed dose.

If you stop taking Adiflox tablets

Do not stop taking Adiflox just because you feel better. It is important that you complete the course of tablets that your doctor has prescribed for you. If you stop taking the tablets too soon, the infection may return, your condition may get worse or bacteria may become resistant to the medicine.

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

4. Possible side effects

Like all medicines, Adiflox can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

Frequency of side effects:

Very common (may affect more than 1/10 patients, which are under treatment with levofloxacin); Common (may affect up to 1/10 patients), Uncommon (may affect up to 1/100 patients), Rare (may affect up to 1/1000 patients), Very rare (may affect up to 1/10 000). With unknown frequency (frequency cannot be estimated from the available data).

Stop taking Adiflox and tell your doctor immediately, or go to the nearest hospital and bring the medicine with you, if occur some of serious allergic reaction symptoms:

Very rare side effects:

- Face or lips oedema, throat swelling, breathing and swallowing difficulties.

If any of the following happen, stop taking Adiflox and tell your doctor immediately, or go to the nearest hospital and bring the medicine with you:

Rare side effects:

- Watery diarrhea which may have blood in it, possibly with stomach cramps and high temperature. This could be signs of a severe bowel problem
- Pain, oedema and/or redness of tendons and ligaments, the Achilles tendon is affected most often.
- Fits, convulsions.

Very rare

- Burning, smarting, formication or numbness - signs of neuropathy

Other side effects:

- Severe itching skin rashes, may affect the mucosa of mouth, nose, eyes or genitals, may be appeared blistering or peeling around mouth and nose.
- Loss of appetite, yellowing of the skin or whites of the eyes, urine darkening, itching, painful stomach (symptoms of liver problems).

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking Adiflox, consult an eye specialist immediately.

Tell your doctor if some of the following side effects appear and continue more than several days or gets serious:

Common side effects:

- Sleeping problems
- Headache, feeling dizzy
- Nausea, vomiting, diarrhea.
- High blood levels of some liver enzymes.

Uncommon side effects:

- Fungus growing (fungus infection) and/or other resistant bacteria
- Changes in the number of white blood cells shown up in the results of some blood tests
- Feeling stressed (anxiety), feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling
- Shortness of breath (dyspnea)
- Changes in the way things taste, loss of appetite, stomach upset or indigestion (dyspepsia), pain in your stomach area, feeling bloated (flatulence) or constipation.
- Itching and skin rash, severe itching or hives (urticarial), sweating too much (hyperhidrosis)
- Joint pain or muscle pain
- Blood tests may show unusual results due to liver (bilirubin increased) or kidney (creatinine increased) problems
- General weakness

Rare side effects:

- Decrease in blood cells (thrombocytes) – aptitude to bruises and bleeding (thrombocytopenia)
- Low number of white blood cells (neutropenia)
- Hypersensitivity (exaggerated immune response)
- In peoples with diabetes – lower levels of blood sugar (hypoglycemia)

- Psychotic reactions (changes in opinion and/or thoughts), hallucinations, a persecution mania (paranoia) with a risk of having suicidal thoughts or actions
- Depression, mental problems, feeling restless (agitation), abnormal dreams or nightmares
- Muscle and joint pain, chest pain, limbs pain.
- Hand and feet tremor (parasthesia).
- Problems with hearing (tinnitus) or eyesight (blurred vision)
- Fast and irregular heart rate (tachycardia) or unusual low blood pressure (hypotension)
- In people with myasthenia gravis (a rare disease of the nervous system) - muscle weakness.
- Changes in the kidney function and occasionally kidney failure which may be due to an allergic kidney reaction (interstitial nephritis)
- Fever

Other side effects include:

- Lowering in red blood cells (anemia); this can make the skin pale or yellow due to damage of the red blood cells; lowering in the number of all types of blood cells (pancytopenia)
- Lowering in the number of white blood cells (agranulocytosis), which lead to fever, sore throat and a general feeling of being unwell that does not go away.
- Loss of circulation (anaphylactic like shock)
- Increase of your blood sugar levels (hyperglycemia) or lowering of your blood sugar levels leading to coma (hypoglycaemic coma). This is important for people that have diabetes.
- Changes in the way things smell, loss of smell or taste (parosmia, anosmia, ageusia)
- Problems moving and walking (dyskinesia, extrapyramidal disorders)
- Temporary loss of consciousness or posture (syncope)
- Temporary loss of vision
- Impairment or loss of hearing
- Abnormal fast heart rhythm, life-threatening irregular heart rhythm including cardiac arrest, alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart)
- Difficulty breathing or wheezing (bronchospasm)
- Allergic lung reactions – inflammation, fever, asthma, cough
- Pancreatitis
- Inflammation of the liver (hepatitis)
- Increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)
- Inflammation of the small blood vessels (allergic vasculitis)
- Inflammation of the tissue inside the mouth (stomatitis)
- Muscle rupture and muscle destruction (rhabdomyolysis)
- Joint redness and swelling (arthritis)
- Pain, including pain in the back, chest and extremities
- Attacks of porphyria (disease affecting the metabolism) in patients with porphyria.
- Persistent headache with or without blurred vision (benign intracranial hypertension)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to Store Adiflox

Store below 25 °C.

Keep out of the sight and reach of children.

Do not use **Adiflox** after the expiry date stated on the blister and carton after EXP.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. Contents of the pack and other information

What Adiflox contains

Active substance – levofloxacin. Each tablet contains 500 mg of levofloxacin.

The other ingredients are:

Tablet core: microcrystalline cellulose, hypromellose, crospovidone, silicified microcrystalline cellulose, sodium stearyl fumarate, silica colloidal anhydrous.

Film coating: talc, titanium dioxide (E171), macrogol, polyvinyl alcohol, sunset yellow (E110), tartrazine (E102), soy lecithin.

What Adiflox looks like and content of the pack:

Adiflox are film – coated tablets for oral use.

The tablets are round, biconvex film – coated tablet with orange color.

7 film-coated tablets are packed in a PVDC/Al foil blister.

One or two blisters are packed in a carton box with patient information leaflet.

Marketing authorization holder and manufacturer:

ADIPHARM EAD
Blvd. Simeonovsko shose 130
Sofia 1700, Bulgaria

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