

**PATIENT INFORMATION LEAFLET****LEVONIC IV 500****SCHEDULING STATUS:**

S4

**PROPRIETARY NAME AND DOSAGE FORM:****LEVONIC IV 500** concentrate for infusion**Read all of this leaflet carefully before you are given LEVONIC IV 500 injection.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **LEVONIC IV 500** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**1. WHAT LEVONIC IV 500 CONTAINS:****Active substance:**

Each 100 ml solution for infusion contains levofloxacin hemihydrate equivalent to 500 mg levofloxacin.

**The other ingredients are:**

Sodium chloride, water for injection.

**2. WHAT LEVONIC IV 500 IS USED FOR:**

**LEVONIC IV 500** is an antibiotic of the fluoroquinolone group of antibiotics which is used to treat various bacterial infections such as sinus and lung infections, urinary tract infections and skin infections.

**3. BEFORE YOU ARE ADMINISTERED LEVONIC IV 500:**

*You should not be administered LEVONIC IV 500:*

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- If you are allergic to levofloxacin or to other active substances that belong to the same group of antibiotics (i.e. quinolones) or to any of the other ingredients of **LEVONIC IV 500** (see “**WHAT LEVONIC IV 500 CONTAINS**”).
- If you have epilepsy or a history of seizures.
- If you have a history of tendon disorders associated with fluoroquinolone antibiotic use.
- If you are under the age of 18 years.
- If you are pregnant or breastfeeding.

***Special care should be taken with LEVONIC IV 500:***

***LEVONIC IV 500 SHOULD NOT BE GIVEN TO YOU IF YOU ARE YOUNGER THAN 18 YEARS OF AGE.***

- If you are prone to seizures.
- If you are taking fenbufen or other non-steroidal anti-inflammatory pain medication.
- If you are taking theophylline used in asthma treatment.
- If you suffer from a disease called pseudomembranous colitis (inflammation of the large intestines).
- If you have tendonitis (inflammation of a tendon) as **LEVONIC IV 500** may aggravate the condition and result in rupturing of a tendon, e.g. in the heel (Achilles tendon).
- If you have porphyria, as **LEVONIC IV 500** may increase the chances of an acute attack.
- If you have a muscle disease called myasthenia gravis as **LEVONIC IV 500** may aggravate symptoms such as joint pains and muscle pains.
- You are exposed to excessive sunlight or sunbeds as **LEVONIC IV 500** may increase your skin's sensitivity to such exposure and result in skin reactions.
- If you are undergoing tuberculosis (TB) testing of your sputum or urine, as **LEVONIC IV 500** may interfere with the results of these tests.

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- If you fall in the following risk groups:
  - Elderly.
  - You have heart disease.
  - You have salt imbalance in the blood (especially low level of potassium or magnesium in the blood).
  - If you were born with or have family history of long QT syndrome (a disorder of the heart's electrical system).
  - You are taking medicines used to treat heart disease, depression or antibiotics from the class macrolides.
- If you are diabetic or suffer from low blood sugar levels and are treated with oral anti-diabetic medicines or insulin.
- If you suffer from peripheral neuropathy (a disease of the nervous system affecting your sense of touch, ability to perform small movements with the hands and feet and causing muscle weakness).
- If you have a family history of or have an actual defect in the liver enzyme called glucose-6-phosphate dehydrogenase (G6PD) (a rare hereditary disease). You are more likely to have serious blood problems when taking **LEVONIC IV 500**.
- If you have kidney problems.

***Pregnancy and breastfeeding:***

***If you are pregnant, planning to become pregnant or breastfeeding your baby while being given this medicine, please consult your doctor, pharmacist or healthcare professional for advice.***

Do not receive **LEVONIC IV 500** if you are pregnant or breastfeeding your baby.

***Driving and using machinery:***

**Do not** drive or use machinery when **LEVONIC IV 500** is administered to you as it may cause drowsiness or dizziness.

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***Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)***

**LEVONIC IV 500** may interact with the following medicines:

- theophylline (used to treat asthma), fenbufen or other non-steroidal anti-inflammatory drugs (used to treat pain and inflammation).
- antidysrhythmics (used to treat heart disease), tricyclic antidepressants (used to treat depression) and macrolides (a class of antibiotics used to treat infections).
- Vitamin K antagonists such as warfarin (used to thin the blood).

Tell your doctor if you are taking any of the above or other medicines before you receive **LEVONIC IV 500**.

**4. HOW TO RECEIVE LEVONIC IV 500:**

**LEVONIC IV 500** is an intravenous injection and will not be prescribed to you for self-administration at home. **LEVONIC IV 500** will be given to you by a doctor or nurse.

**LEVONIC IV 500** will be administered to you once or twice a day.

The dose (strength) of **LEVONIC IV 500** that you will receive as well as the duration of treatment with **LEVONIC IV 500** will be determined by your doctor.

This depends on a number of factors, including:

- the severity and type of infection you are suffering from and for which you are being treated with **LEVONIC IV 500**
- your size (body weight and height)
- whether or not you are also taking other medicines

***If you receive more LEVONIC IV 500 than you should:***

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Since your doctor or a nurse will administer **LEVONIC IV 500**, he/she will control the dosage.

However, in the event of overdosage, your doctor will treat the side-effects symptomatically.

***If you missed a dose of LEVONIC IV 500:***

Your doctor or nurse will make sure you receive **LEVONIC IV 500** at the right time. If you think that you have missed a dose, tell your doctor or nurse.

**5. POSSIBLE SIDE EFFECTS:**

**LEVONIC IV 500 can have side effects.**

*Not all side effects reported for LEVONIC IV 500 are included in this leaflet. Should your general health worsen while being treated with LEVONIC IV 500, please consult your doctor, pharmacist or other healthcare professional for advice.*

**Treatment with LEVONIC IV 500 should be stopped immediately, should the following side effects occur:**

- Serious allergic reactions including skin reactions, fever, low blood pressure (dizziness), allergic pneumonitis (cough or other lung symptoms), shock (cold, clammy skin, irregular breathing, weakness, anxiety).
- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty breathing.
- Hepatitis (yellowing of the skin and the whites of the eyes).
- Restlessness, anxiety, changes in mood, confusion.
- Convulsions (seizures), extrapyramidal symptoms including akinesia (inability to initiate movement) and akathisia (inability to remain motionless), paraesthesia (heavy or sleepy feeling or sense of needles and pins in the lower part of the body, including the legs).
- Inflammation and tear of a tendon or tendons.
- Diarrhoea with bloody stools.

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- Inform your doctor as soon as possible if any of the following side effects occur:
  - Headache, dizziness, sleep disturbances, taste disturbances, trembling or shaking, hallucinations (seeing or hearing things that are not there).

**Other side-effects of LEVONIC IV 500 that should be treated as soon as possible, include the following:**

- Nausea, vomiting, diarrhoea, loss of appetite and stomach upset or stomach pain.
- Vision, hearing or smell disturbances.
- Kidney problems.
- Skin reactions when exposed to sunlight or sunbeds, rash, itching, hives or wheals.
- Arthralgia (joint pains), myalgia (muscle pain), muscle weakness.
- Low blood sugar levels.
- Increased heart rate.
- Low blood pressure.
- Shortness of breath, tight chest.
- Thrush.

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

**6. STORAGE AND DISPOSING OF LEVONIC IV 500:**

- Store at or below 25 °C. Protect from light. Keep in outer container until required for use. Do not refrigerate. The solution should be used within 3 hours after perforation of the opening in the bag to prevent contamination.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.