

## **SCHEDULING STATUS**

S4

## **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

**LEVOJUB 250** film coated tablet

**LEVOJUB 500** film coated tablet

### **Read all of this leaflet carefully before you start taking LEVOJUB:**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **LEVOJUB** 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 LEVOJUB CONTAINS:**

### **Active ingredient:**

Each film coated **LEVOJUB 250** tablet contains levofloxacin hemihydrate equivalent to 250 mg levofloxacin.

Each film coated **LEVOJUB 500** tablet contains levofloxacin hemihydrate equivalent to 500 mg levofloxacin.

### **Inactive ingredients:**

Crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, Opadry Pink (containing hypromellose, iron oxide red, iron oxide yellow, macrogol, talc, titanium dioxide), talc. Sugar free.

## **2. WHAT LEVOJUB IS USED FOR:**

**LEVOJUB** belongs to the class of medicines known as fluoroquinolone antibiotics. It is used to treat bacterial infections.

### 3. BEFORE YOU TAKE LEVOJUB:

#### Do not take LEVOJUB:

- If you are hypersensitive (allergic) to levofloxacin, any other quinolone antibiotics, or any of the other ingredients of **LEVOJUB** (see **WHAT LEVOJUB CONTAINS**).
- If you suffer from epilepsy (fits/seizures).
- If you have ever had tendon (ligament) problems related to treatment with a fluoroquinolone antibiotic.
- If you are a child or adolescent under 18 years of age.
- If you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**).

#### Take special care with LEVOJUB:

Stop taking **LEVOJUB** immediately and tell your doctor:

- If you experience symptoms such as swelling of the face and tongue, skin sensitivity, hives, a red or purple skin rash that spreads within hours to days, blisters on your skin and the mucous membranes of your mouth, nose, eyes and genitals, or shedding of your skin while taking **LEVOJUB**.

Tell your doctor immediately if:

- You develop diarrhoea after taking **LEVOJUB** and this becomes severe or persistent or you notice that your stools contain blood or mucus.
- You develop liver problems with symptoms such as yellowing of the skin and eyes, abdominal pain and swelling, dark coloured urine, pale stool, bloody or tarry stool, chronic tiredness, nausea (feeling sick) or vomiting (being sick) and loss of appetite.
- You have or ever have had heart problems. Caution should be taken when taking **LEVOJUB** if you were born with or have a family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in your blood (especially low levels of potassium or magnesium in your blood), have a very slow heart rhythm (called bradycardia), have a history of heart disease, have a history of a heart attack (myocardial infarction) or if

you are taking other medicines that result in abnormal ECG changes (see section **Taking other medicines with LEVOJUB**).

- You develop symptoms such as tingling in your hands or feet, sharp, stabbing pains, numbness in hands or feet, feeling of heaviness in the arms and legs (sometimes it may feel like your legs or arms are locked in place) while taking **LEVOJUB**.
- You have ever had mental health problems.
- You are prone to seizures (fits).
- You have a muscle disease called myasthenia gravis.
- You experience pain at the back of your lower leg or swelling of the ankle or foot while taking **LEVOJUB**. If you are an elderly person using corticosteroids, also called steroids, you have a higher risk of experiencing pain at the back of your lower leg or swelling of the ankle or foot while taking **LEVOJUB**.
- You experience any problems with your vision, like blurred vision, while taking **LEVOJUB**. Consult an eye specialist immediately.
- You have kidney problems.

In addition:

- If you have diabetes (high blood sugar), **LEVOJUB** may cause high or low blood sugar (especially if you are taking diabetic medicine or using insulin), and may even lead to a diabetic coma. Make sure you monitor your blood glucose levels carefully.
- If you have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), tell your doctor, who will advise you whether **LEVOJUB** is suitable for you.
- Some people who take **LEVOJUB** may become more sensitive to sunlight than they normally are. Exposure to sunlight, even for brief periods of time, may cause severe sunburn or skin rash, redness, itching, or discolouration. When you begin taking **LEVOJUB**, stay out of direct sunlight and do not use a sunbed.
- Please tell your doctor that you are taking **LEVOJUB** if you are undergoing tuberculosis (TB) testing, as **LEVOJUB** may interfere with the results of these tests.

**Taking LEVOJUB with food and drink:**

**LEVOJUB** may be taken with meals or on an empty stomach.

**Pregnancy and breastfeeding:**

Do not take **LEVOJUB** if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LEVOJUB**.

**Driving and using machinery:**

**LEVOJUB** may cause some people to become dizzy, light-headed, drowsy or less alert than they normally are. Make sure you know how you react to **LEVOJUB** before you drive a vehicle, operate machines or do anything else that could be dangerous if you are dizzy or are not alert. If these reactions are especially bothersome, consult your doctor.

**Using other medicines with LEVOJUB:**

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

Do not take the following medicines at the same time as **LEVOJUB**:

- Iron salts (supplement, used in the treatment of anaemia).
- Zinc salts (supplement, used in the treatment of common cold).
- Didanosine (antiretroviral medicine, used in the treatment of HIV/AIDS).
- Sucralfate (used in the treatment of ulcers in the gastrointestinal tract).
- Magnesium- or aluminium-containing antacids (used to treat heartburn).

Take these medicines at least 2 hours before or after taking your **LEVOJUB** tablets.

Tell your doctor if you are using the following medicines which may cause an interaction when used in combination with **LEVOJUB**:

- Antidiabetic medicine (used in the treatment of high blood sugar (diabetes)).
- Theophylline (used to treat asthma).

- Medicines used to treat pain and inflammation (such as aspirin, ibuprofen, fenbufen and indomethacin).
- Probenecid (used to treat gout) and cimetidine (used for ulcers and heartburn), especially if you suffer from kidney problems.
- Corticosteroids ((also known as steroids) anti-inflammatory medicine prescribed for a wide range of conditions, such as allergies, skin problems, asthma or arthritis).
- Ciclosporin (used after organ transplants to prevent organ rejection).
- Warfarin (used to prevent blood from clotting).
- Medicines that affect the way your heart beats. This includes medicines for:
  - Abnormal heart rhythm (such as quinidine, hydroquinidine, disopyramide, sotalol and amiodarone).
  - Depression (such as amitriptyline and imipramine).
  - Psychiatric disorders.
  - Tizanidine (used to treat spasms, cramping and tightness of muscles).
  - Bacterial infections (such as erythromycin, azithromycin, clarithromycin).

#### **4. HOW TO TAKE LEVOJUB:**

Do not share medicines prescribed for you with any other person.

Always take **LEVOJUB** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 250 mg or 500 mg taken once or twice daily.

Swallow the tablets whole, without breaking, crushing, or chewing them.

Your doctor will determine your dosage depending on your condition.

#### **If you take more LEVOJUB than you should:**

The consequences of an overdose include central nervous system symptoms such as confusion, dizziness, impairment of consciousness and convulsions (seizures).

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining tablets with you, so that the

doctor knows what you have taken.

**If you forget to take LEVOJUB:**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your **LEVOJUB** tablets at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

**5. POSSIBLE SIDE EFFECTS:**

**LEVOJUB** can have side effects.

Not all side effects reported for **LEVOJUB** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LEVOJUB**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens stop taking **LEVOJUB** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your face, lips, mouth, tongue, eyes or throat (angioedema).
- Difficulty breathing, dizziness (severe hypersensitivity).
- Rash or itching.
- Blistering of the skin, mouth, eyes and genitals.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **LEVOJUB**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Less frequent:*

- Diarrhoea with bloody stools.
- Unusual fast or slow beating of your heart.
- Restlessness, trembling or shaking, convulsions (fits), agitation, depression (changes in

mood), confusion, hallucinations, feeling very suspicious.

- Pain and inflammation in your tendons. In some cases, the tendon can rupture.
- Fever, low blood pressure (dizziness), light-headedness, cough or other lung symptoms, shock (cold, clammy skin, irregular breathing, weakness, anxiety).
- Hepatitis (yellowing of the skin and the whites of the eyes).
- Blood tests showing an increase in liver enzymes.
- Loss of appetite, yellowing of skin and eyes, dark-coloured urine or a tender stomach which may be signs of liver problems.
- Kidney infection and kidney failure.
- Difficulty in breathing, shortness of breath.
- Low or high blood sugar levels (especially if you have diabetes) or diabetic coma.

*Frequency unknown:*

- Thoughts of harming or killing yourself.
- Abnormal electroencephalogram (an electroencephalogram is a record of the electrical activity of your brain, as recorded by an electroencephalograph).
- Unsteady walking, numbness and tingling of the fingers and toes.
- Encephalopathy (a disease affecting the function or structure of your brain).
- QT prolongation (characterised by an abnormal change in the electrical activity of your heart that can increase the risk of a fatal heart rhythm known as torsades de pointes).
- Inflammation of the pancreas which causes severe pain in the abdomen and back.
- Inflammation of the lungs which causes wheezing, breathlessness, cough and raised temperature.
- Vision loss.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent:*

- Blood test results showing changes in the number of disease fighting white blood cells, which

may put you at risk for infection.

- Sleeping problems, inability to sleep.
- Nausea (feeling sick), vomiting (being sick), diarrhoea, indigestion and stomach pain or discomfort.
- Headaches, dizziness.

*Less frequent:*

- Bloating feeling, constipation.
- Blood test results showing a condition where there is a reduction in the number of red blood cells, as well as platelets. This can cause weakness, bruising, frequent infections, pale skin, tiredness, breathlessness and dark urine.
- Disturbances of the senses of taste and smell.
- Loss of appetite.
- Ringing in the ears.
- Blurred vision.
- Oedema (excessive build-up of fluid in your body's tissues, leading to swelling of your ankles and feet).
- Eye inflammation and increased tear production.
- Lack of energy and strength.
- Skin sensitivity when exposed to sunlight or sunbeds.
- Muscle pain and weakness.
- Fungal growth (thrush).
- Myasthenia gravis (an auto immune disease causing fatigue and muscle weakness).

*Frequency unknown:*

- Pains (back, chest, arms or legs).
- Difficulty hearing.
- Inflammation of the mouth.
- Increased international normalised ratio (INR) (you may bruise easily, have frequent

nosebleeds or notice your gums bleeding).

- Inflammation of a blood vessel (characterised by fever, headache, fatigue, weight loss and general pains), vasodilatation (widening of blood vessels, leading to low blood pressure).
- Dysphonia (hoarse voice, difficulty speaking).
- Multiple-system organ failure (a serious condition in which two or more of your organs are not functioning normally).

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

#### **6. STORING AND DISPOSING OF LEVOJUB:**

- Store at or below 25 °C in a dry place. Protect from light.
- Keep blister strips in the carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

#### **7. PRESENTATION OF LEVOJUB:**

**LEVOJUB 250:** Blister pack comprising of a lidding foil made up of plain aluminium foil coated with heat sealable lacquer and base film made up of clear, colourless PVC.

Pack sizes: 5 or 30 tablets per carton.

**LEVOJUB 500:** Blister pack comprising of a lidding foil made up of plain aluminium foil coated with heat sealable lacquer and base film made up of clear, colourless PVC.

Pack sizes: 5 or 30 tablets per carton.

#### **8. IDENTIFICATION OF LEVOJUB:**

**LEVOJUB 250:** Light peach coloured, capsule-shaped, film coated tablet, scored on both sides and debossed with “J” and “250” on either side of the score line on one side of tablet.

**LEVOJUB 500:** Light peach coloured, capsule-shaped, film coated tablet, scored on both sides and debossed with “J” and “500” on either side of the score line on one side of tablet.

**9. REGISTRATION NUMBERS**

**LEVOJUB 250:** 46/20.1.1/0977

**LEVOJUB 500:** 46/20.1.1/0978

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Jubilant Pharma SA (Pty) Ltd.

24 Parrot Avenue

Extension 1, Lenasia

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**11. DATE OF PUBLICATION**

23 November 2017