

PATIENT INFORMATION LEAFLET FOR

LEVOFLOXACIN UNICORN 250 / 500

SCHEDULING STATUS

S4

LEVOFLOXACIN UNICORN 250 film coated tablet

LEVOFLOXACIN UNICORN 500 film coated tablet

Read all of this leaflet carefully before you start taking LEVOFLOXACIN

UNICORN:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **LEVOFLOXACIN UNICORN** 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.

What is in this leaflet:

1. *What LEVOFLOXACIN UNICORN is and what it is used for*
2. *What you need to know before you take LEVOFLOXACIN UNICORN*
3. *How to take LEVOFLOXACIN UNICORN*
4. *Possible side effects*
5. *How to store LEVOFLOXACIN UNICORN*
6. *Contents of the pack and other information*



1. WHAT LEVOFLOXACIN UNICORN IS AND WHAT IT IS USED FOR

LEVOFLOXACIN UNICORN belongs to the class of medicines known as fluoroquinolone antibiotics. It is used to treat the following bacterial infections: bronchitis, pneumonia, sinusitis, urinary tract infections, skin and soft tissue infections and stomach infections. **LEVOFLOXACIN UNICORN** works by killing bacteria.

2. What you need to know before you take LEVOFLOXACIN UNICORN

LEVOFLOXACIN UNICORN can cause serious side effects or even cause death. Side effects include:

- Tendon rupture (breakage) or swelling of the tendon (tendinitis).
 - Tendons are tough cords of tissue that connect muscles to bones.
 - Pain, swelling, tears, and inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites may occur.
- The risk of experiencing tendon problems is higher if you:
- Over the age of 60 years old
 - Are using a medicine called a corticosteroid
 - Have had a kidney, heart or lung transplant
 - Do strenuous physical activity or exercise
 - Have kidney failure
 - Had tendon problems in the past, such as rheumatoid arthritis.

If you experience any of the following serious side effects, speak to your doctor immediately.

Do not take LEVOFLOXACIN UNICORN:

- If you are hypersensitive (allergic) to levofloxacin, any other quinolone antibiotics, or any of the other ingredients of **LEVOFLOXACIN UNICORN** (see **WHAT LEVOFLOXACIN UNICORN 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**).
- If you are currently taking medicines to control your high blood pressure called ACE inhibitors/angiotensin- receptor blockers, especially if you have kidney disease or you are over the age of 60 years old.
- If you have a damaged mitral and/or aortic heart valve which cannot close properly.

Take special care with LEVOFLOXACIN UNICORN:

- If you experience pain at the back of your lower leg or swelling of the ankle or foot while taking **LEVOFLOXACIN UNICORN**. If you are an elderly person, using corticosteroids, also called steroids, or if you had a kidney, lung or heart transplant; you have a higher risk of experiencing pain at the back of your lower leg or swelling of the ankle or foot while taking **LEVOFLOXACIN UNICORN**.
- 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 **LEVOFLOXACIN UNICORN**. Stop taking **LEVOFLOXACIN UNICORN** immediately and tell your doctor.
- If you develop diarrhoea after taking **LEVOFLOXACIN UNICORN**. If this becomes severe or persistent or you notice that your stools contain blood or mucus.



- If 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.
- If you have or ever have had heart problems. Caution should be taken when taking **LEVOFLOXACIN UNICORN** 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 LEVOFLOXACIN UNICORN**).
- If 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 **LEVOFLOXACIN UNICORN**.
- If you have ever had mental health problems.
- If you are prone to seizures (fits).
- If you have a muscle disease called myasthenia gravis.
- If you experience any problems with your vision, like blurred vision, while taking **LEVOFLOXACIN UNICORN**. Consult an eye specialist immediately.
- If you have kidney problems.
- If you have diabetes (high blood sugar), **LEVOFLOXACIN UNICORN** 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 **LEVOFLOXACIN UNICORN** is suitable for you.
- Some people who take **LEVOFLOXACIN UNICORN** may become more sensitive to sunlight than they are normally. Exposure to sunlight, even for brief periods of time, may cause severe sunburn or skin rash, redness, itching, or discolouration. When you begin taking **LEVOFLOXACIN UNICORN**, stay out of direct sunlight and do not use a sunbed.
- If you are taking a medicine known as a Vitamin K antagonist (for example, warfarin). This medicine in combination with **LEVOFLOXACIN UNICORN** may cause bleeding. Your doctor will continuously monitor your blood while you are using these medicines together.
- Please tell your doctor that you are taking **LEVOFLOXACIN UNICORN** if you are undergoing tuberculosis (TB) or urine testing for opiates (such as heroine or codeine) testing, as **LEVOFLOXACIN UNICORN** may interfere with the results of these tests.
- If you are using **LEVOFLOXACIN UNICORN** for a prolonged period, you may develop an infection after or on top of the existing infection being treated.
- If you have been diagnosed with a damaged mitral and/or aortic heart valve which cannot close properly.

Using other medicines with LEVOFLOXACIN UNICORN:

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 **LEVOFLOXACIN**

UNICORN:

- Iron salts (supplement, used in the treatment of anaemia).
- Sucralfate (used in the treatment of ulcers in the gastro-intestinal tract).
- Magnesium- or aluminium- containing antacids (used to treat heartburn).

Take these medicines at least 2 hours before or after taking your

LEVOFLOXACIN UNICORN tablets.

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

- 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.
- 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.
 - Bacterial infections (such as erythromycin, azithromycin, clarithromycin).
- ACE inhibitors or angiotensin blockers – these are medicines used to control your blood pressure. Ask your healthcare provider if you are unsure.

Taking LEVOFLOXACIN UNICORN with food and drink:

LEVOFLOXACIN UNICORN may be taken with meals or on an empty stomach.



Pregnancy and breastfeeding:

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

LEVOFLOXACIN UNICORN.

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

Driving and using machinery:

LEVOFLOXACIN UNICORN may cause you to become dizzy, light-headed, drowsy or less alert than they are normally. Make sure you know how you react to **LEVOFLOXACIN UNICORN** 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.

3. HOW TO TAKE LEVOFLOXACIN UNICORN:

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

Always take **LEVOFLOXACIN UNICORN** 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.

Take **LEVOFLOXACIN UNICORN** two hours before an antacid, or a medicine that contains iron or sucralfate.

The dose of **LEVOFLOXACIN UNICORN** will be different for different patients.

Follow your doctor's orders or the directions on the label.



If you take more LEVOFLOXACIN UNICORN 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 LEVOFLOXACIN UNICORN:

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 you **LEVOFLOXACIN UNICORN** tablets at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

LEVOFLOXACIN UNICORN can have side effects.

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

If any of the following happens stop taking **LEVOFLOXACIN UNICORN** 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 **LEVOFLOXACIN UNICORN**. 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), 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.

Frequency unknown:

- Thoughts of harming or killing yourself.
- Unsteady walking, numbness and tingling of the fingers and toes.
- 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.
- Low or high blood sugar levels (especially if you have diabetes) or diabetic coma.

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

Tell your doctor if you notice any of the following:

Frequent:

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

Less frequent:

- Bloating feeling, constipation.
- Blood test results showing changes in the number of disease fighting white blood cells, which may put you at risk for infection.
- 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 and hearing loss.
- Inflammation of the mouth.
- Damaged mitral and/or aortic heart valve which cannot close properly.

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

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of LEVOFLOXACIN UNICORN.



5. HOW TO STORE LEVOFLOXACIN UNICORN:

- 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).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What LEVOFLOXACIN UNICORN contains

Active ingredient:

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

Each film coated **LEVOFLOXACIN UNICORN 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.

What LEVOFLOXACIN UNICORN looks like and contents of the pack

LEVOFLOXACIN UNICORN 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.

LEVOFLOXACIN UNICORN 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.

LEVOFLOXACIN UNICORN 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 transparent PVC. 10 x tablets per blister strip.

LEVOFLOXACIN UNICORN 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 transparent PVC. 10 x tablets per blister strip.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

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8000

South Africa

REGISTRATION NUMBERS

LEVOFLOXACIN UNICORN 250: 46/20.1.1/0944

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