

Remflox 250mg Film-Coated Tablet

Levofloxacin hemihydrate 256.23mg eq. to Levofloxacin 250mg

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What Remflox 250mg Film-Coated Tablets is used for

Remflox 250mg Film-Coated Tablets is an oral antibacterial agent used to treat adults with certain kinds of infection.

How Remflox 250mg Film-Coated Tablets works

Remflox 250mg Film-Coated Tablets interferes with bacterial enzymes to prevent bacterial growth, thereby killing the susceptible bacteria.

Before you take Remflox 250mg Film-Coated Tablets

- When you must not take it

Do not take Remflox 250mg Film-Coated Tablets if you are under 18 years of age.

You should not take Remflox 250mg Film-Coated Tablets if you are allergic to any of the group of antibiotics known as quinolones.

You should not take Remflox 250mg Film-Coated Tablets if you have had

tendinitis or tendon rupture while taking quinolone antibiotics.

Pregnancy and Breastfeeding

Do not take Remflox 250mg Film-Coated Tablets if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Remflox 250mg Film-Coated Tablets, stop taking it immediately and contact your doctor.

Do not take Remflox 250mg Film-Coated Tablets if you are breastfeeding.

- Before you start to take it

It is important to let your doctor know if you have decreased kidney function, epilepsy or have a history of seizures, problems with heart rhythm, heart rate, or taking anti-diabetic drugs.

Tell your healthcare providers if you have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm). Tell your healthcare providers if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).

Tell your healthcare providers if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis).

You should not take fluoroquinolone antibacterial medicines, including

Remflox 250mg Film-Coated Tablets, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

Remflox 250mg Film-Coated Tablets should be administered with care when co-administered with the following drugs: non-steroidal anti-inflammatory drugs, anti-diabetic drugs and anti-coagulants (warfarin). Remflox 250mg Film-Coated Tablets should be taken at least 2 hours before or after taking antacids, sucralfate or multi-vitamins.

How to take Remflox 250mg Film-Coated Tablets

- How much to use

A tablet of 250mg or 500mg once a day.

- When to use it

Each tablet should be swallowed whole and may be taken with or without food.

- How long to use it

As prescribed by your doctor.

- If you forget to use it

Take the missed dose as soon as you remember. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or

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poisoning. You may need urgent medical attention.

While you are taking RemfloX 250mg Film-Coated Tablets

- Things you must do

You should complete the full course of medication. You should drink fluids liberally to maintain a hydrated condition.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not start a new medicine without first consulting a doctor.

- Things to be careful of

Since symptoms (e.g. disturbance of consciousness) may occur during RemfloX 250mg Film-Coated Tablets treatment, you should be careful while operating dangerous machine, such as driving a motor vehicle.

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including RemfloX 250mg Film-Coated Tablets, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area

until you can see your healthcare providers.

- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of RemfloX 250mg Film-Coated Tablets therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking RemfloX 250mg Film-Coated Tablets, contact your healthcare providers and rest the painful area.

Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking RemfloX 250mg Film-Coated Tablets and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including RemfloX 250mg Film-Coated Tablets for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts. If you develop such reactions, stop taking/ using RemfloX 250mg Film-Coated Tablets and inform your doctor immediately.

Side effects

RemfloX 250mg Film-Coated Tablets is generally well tolerated. The main adverse events include nausea, diarrhea, abdominal pain, insomnia, dizziness and rash.

Rare: Change in your opinion and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions, hallucination, depression.

Very rare: Psychotic behaviour

Not known (frequency cannot be estimated from the available data): Psychotic reactions with a risk of having suicidal thoughts or actions.

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Ruptures of shoulder, hand, or Achilles tendons have been reported in patients receiving quinolones, including Remflox 250mg Film-Coated Tablets. If you develop pain, swelling, or rupture of a tendon you should stop taking Remflox 250mg Film-Coated Tablets and contact your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section “Before you start to take Remflox 250mg Film-Coated Tablets” and “Things to be careful of”).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Remflox 250mg Film-Coated Tablets

- Storage

Do not store above 30°C. Keep the tablets in blister in the provided carton to protect from light and moisture.

Keep out of reach of children.

Do not use Remflox 250mg Film-Coated Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

- Disposal

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.

Product Description

- What it looks like

Remflox 250mg Film-Coated Tablets are film coated tablets for oral use. The tablets are oblong and scored with pink colour.

The tablets are provided in pack size of 10 tablets.

- Ingredients

- Active ingredient: Levofloxacin (as hemihydrate)
- Inactive ingredients: Microcrystalline cellulose, Crospovidone, Hypromellose, Sodium Stearyl Fumarate, Opadry Complete Film Coating System 02F240040 containing Hypromellose, Titanium dioxide (E171), Talc, Macrogol, Yellow Ferric Oxide (E172) and Red ferric oxide (E172)

- MAL number:

MALXXX

Manufacturer

Remington Pharmaceutical Industries (Pvt) Ltd.
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Product Registration Holder

Pharmaforte (M) Sdn. Bhd.
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Date of revision

03/2025

Serial Number

NPRA (R2) 24/119