

IFICIPRO 250/500

Ciprofloxacin Hydrochloride Tablet USP (250mg and 500mg)

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What IFICIPRO is used for

IFICIPRO can be used to treat or prevent certain infections caused by bacteria: Infections of the respiratory tract, urinary tract, gastrointestinal (GI), skin and soft tissues, bones and joints. Bacteria in the blood (Septicemia), inflammation of the inner wall of the abdomen (peritonitis), infection in patients with reduced immunity.

How IFICIPRO works

Ificipro contains ciprofloxacin as active ingredient. It belongs to a group of antibiotics called fluoroquinolone.

Antibiotics kill the bacteria or germ which causes infections.

Before you use IFICIPRO

When you must not use it

Do not take IFICIPRO if you:

Ever had a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.

- Before you start to use it

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

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You must not take IFICIPRO if you are pregnant or think you might be.

- Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal and dietary supplements. IFICIPRO and other medicines can affect each other causing side effects. Especially tell your healthcare provider if you take:

- Products that contain caffeine or theophylline (medicine to treat asthma or lungs).
- Duodenal ulcers medicine (eg Sucralfate), antiretroviral medicine (eg didanosine), an antacid, multivitamin, or other product that has magnesium, calcium, aluminum, iron, or zinc.
- Antiepileptic (anticonvulsants, medicine for the treatment of seizures).
- Sulfonylurea glyburide (antidiabetic medicines).
- Immunosuppressant medicine (medicines that dampen down the activity of the body’s immune system) (cyclosporine).
- The oral anticoagulant (medicines that prevent blood clotting) warfarin or its derivatives.
- Medication for gout (Probenecid)

- Medication to treat arthritis and rheumatic condition (Methotrexate).
- A Non-Steroidal Anti-Inflammatory Drug, NSAIDs (usually for the treatment of pain) in combination of very high doses of quinolones.
- Metoclopramide (medication to treat nausea) Ask your healthcare provider if you are not sure if any of your medicines are listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How to use IFICIPRO

- How much to use

Follow all directions. Your healthcare provider will prescribe a suitable dose for you base on the type and severity of infection that you have. Take IFICIPRO exactly as prescribed by your healthcare provider.

- When to use it

Take IFICIPRO as prescribed by your healthcare provider. Swallow the tablet whole. Do not split, crush, or chew the tablet. Tell your healthcare provider if you cannot swallow the tablet whole. Drink plenty of fluids while taking IFICIPRO.

- How long to use it

Do not skip any doses, or stop taking IFICIPRO even if you begin to feel better, until you finish your prescribed treatment. You must consult your healthcare provider before stopping.

- If you forget to use it

If you miss a dose of IFICIPRO, take it as soon as you remember, if it is near the next dose you should skip the missed dose and not do double up doses.

- If you use too much (overdose)

If you take too much, call your healthcare provider or get medical help immediately. In the event of acute overdosage, reversible renal

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toxicity has been reported in some cases.

While you are using it

- Things you must do

Drink more water to maintain your body hydration to prevent the formation of highly concentrated urine. Tell your healthcare provider about side effect occurs while taking ciprofloxacin. Your doctor will decide whether treatment with ciprofloxacin needs to be stopped.

- Things you must not do

IFICIPRO can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how affects you.

- Things to be careful of

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

Prolonged, disabling and potentially irreversible

Fluoroquinolone antibacterial medicines, including IFICIPRO, 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 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 shoulders, 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 IFICIPRO therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking IFICIPRO, 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 IFICIPRO and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Side effects

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 use it and Things to be careful of).

Body as a whole: headache, abdominal pain/discomfort, foot pain, pain, pain in extremities.

Cardiovascular: palpitation (fast heart rate), atrial flutter (abnormality in the

beating of the heart), ventricular ectopy (extra heartbeat that originates from the lower chamber of the heart), syncope (fainting), hypertension (high blood pressure)

Central nervous system: restlessness, dizziness, insomnia (difficulty in sleeping), nightmares

Gastrointestinal: painful oral mucosa, dysphagia (difficulty in swallowing), gastrointestinal bleeding

Musculoskeletal: arthralgia (joint pain) or back pain, joint stiffness, neck or chest pain

Renal/urogenital: interstitial nephritis (Inflammation of the kidney in which the interstitial connective tissue is chiefly affected)

Respiratory: dyspnea (difficulty in breathing), epistaxis (nose bleed), laryngeal or pulmonary edema (Abnormal buildup of fluid in the lung)

Skin/hypersensitivity: allergic reaction, pruritus (itching), edema of the face, neck, lips, hyperpigmentation.

Special senses: blurred vision, disturbed vision (change in color perception, over brightness of lights), decreased visual acuity, diplopia (double vision), eye pain, tinnitus (ringing in the ear), hearing loss.

If you encounter any other side effects not mention here, please refer to your healthcare provider.

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

Storage and Disposal of IFICIPRO

- Storage

Store at a temperature not exceeding 30°C.

Keep IFICIPRO 200/500mg and all medicines out of the reach of children. The expiry date of this medicinal product is printed on the box and blister foil. Do not use this medicinal product after the expiry date.

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- Disposal

Medicines should not be disposed of via waste water 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

IFICIPRO 250/500 MG

IFICIPRO 250/500 mg Film Coated Tablets is White to yellowish white, round biconvex film coated tablet. Blister packed in PVC/Aluminum blister and packed in card box (packs of 10x10's)

- Ingredients

- Active ingredient

IFICIPRO 250/500 mg: Each tablet contains Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin 250/500 mg

- Inactive ingredients

Opadry white, Sodium starch glycolate, Colloidal silicon dioxide, Talc, Microcrystalline cellulose, Magnesium Stearate, Maize starch, Purified water

- MAL number(s):

MAL08111828AZ

Manufacturer and Product Registration Holder

- **Manufacturer**

Unique Pharmaceutical Laboratories
(A Div. of J.B. Chemicals and Pharmaceuticals Ltd)
Plot No. 215 – 219, G.I.D.C. Industrial Area, Panoli, Dist. Bharuch, 394 116, India.

- **Product Registration Holder**

Unimed Sdn. Bhd.,
53, Jalan Tembaga SD5/2B, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia.

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