

OFCIN FILM COATED TABLET

Ofloxacin (200mg, 400mg)

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What OFCIN F.C TABLET is used for

OFCIN F.C TABLET is used to treat infections caused by susceptible strains of microorganisms in infections of the urinary tract, lower respiratory tract, skin and soft tissue, gonorrhea and non-gonococcal urethritis and cervicitis.

How OFCIN F.C TABLET works

OFCIN F.C TABLET inhibits DNA gyrase, an enzyme necessary for bacterial DNA replication, in susceptible organisms. It is active *in vitro* against many Gram-positive aerobic bacteria. It is also active *in vitro* against most Gram-negative aerobic bacteria.

Before you use OFCIN F. C. TABLET

- When you must not take it
Do not take OFCIN F.C TABLET if you have known hypersensitivity to any component of OFCIN F.C TABLET or to other quinolone antibiotics. OFCIN F.C TABLET contraindicated in patients with a history of epilepsy or with a lowered seizure threshold. OFCIN F.C TABLET is also contraindicated in children or growing adolescents and in pregnant or breast-feeding women.

- Before you start to use it
Tell your doctor or pharmacist if you are allergic to any medicines or if you have any other medical conditions.

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, Behçet’s disease, high blood pressure, or known atherosclerosis).

You should not take fluoroquinolone antibacterial medicines, including OFCIN F.C TABLET, 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
Do not take OFCIN F.C TABLET concurrently with antacids, sucralfate, oral antidiabetics, warfarin, theophylline, aminoglycosides, beta-lactam antibiotics and antimycobacterial agents. Seek for your doctor or pharmacist advice if you are taking any of the medication mentioned or other medicines, including those you have bought without a prescription.

How to use OFCIN F. C. TABLET

- How much to use
Tablet should be taken according to the dose prescribed by your doctor or pharmacist.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information

contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use OFCIN F.C TABLET for the duration that the doctor recommends.

- If you forgot to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you take 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 used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using OFCIN F.C TABLET.

Take OFCIN F.C TABLET only with a doctor’s prescription.

- Things you must not do

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

Do not use any new medicines without consulting your doctor or pharmacist.

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Do not give OFCIN F.C TABLET to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including OFCIN F.C TABLET 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 OFCIN F.C TABLET and inform your doctor immediately.

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 OFCIN F.C TABLET, 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 OFCIN F.C TABLET therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking OFCIN F.C TABLET, 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 OFCIN F.C TABLET and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Side effects

Like all medicines, OFCIN F.C TABLET can cause side effects, although not everybody gets them.

Rare: Depression (potentially leading to thoughts of suicide, suicide attempts, or completed suicide), or hallucinations.

Very rare: Psychotic reactions potentially leading to thoughts of suicide, suicide attempts, or completed suicide.

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).

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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) or Vaccines (AEFI)]

Storage and Disposal of OFCIN F.C TABLET

- Storage

Store below 30°C, protect from light & moisture.

- 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

OFCIN F.C TABLET is a slight orange color film coated round tablet.

- Ingredients

- Active ingredient- Ofloxacin

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Ofloxacin (200mg, 400mg)

- Inactive ingredients-

Lactose

Cellulose

Sodium Starch Glycolate

Magnesium Stearate

Polyethylene Glycol

Talc

Dimethylpolysiloxane

Titanium Dioxide

Iron Oxide Red

Iron Oxide Yellow

MAL number(s)

Ofcin F.C Tablet 200mg

MAL20020256AZ

Ofcin F.C Tablet 400mg

MAL20020257AZ

**Manufacturer and Product
Registration Holder**

Y.S.P. Industries (M) Sdn. Bhd.

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