

CIFLOX[®] FILM COATED TABLET

Ciprofloxacin (250mg, 500mg, 750mg)

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What CIFLOX[®] FILM COATED TABLET is used for

CIFLOX[®] FILM COATED TABLET is used for the treatment of infections caused by susceptible strains of the designated microorganisms listed in the product insert. Please consult your doctor before taking this medicine.

How CIFLOX[®] FILM COATED TABLET works

CIFLOX[®] FILM COATED TABLET belongs to the group of fluoroquinolone antibiotics that kills bacteria by blocking the two types of enzymes which are essential for the growth and replication of bacteria.

Before you use CIFLOX[®] FILM COATED TABLET

- When you must not use it

You must not use this medicine if you are allergic to the ingredient or any other combinations of this medicine. You should not use CIFLOX[®] FILM COATED TABLET together with medicine that contains tizanidine, antacids, probenecid, methotrexate, theophylline, warfarin, ropinirole and clozapine.

- Before you start to use it

Tell your doctor if you have allergies to any medicines or if you have any 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-Danlons 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 CIFLOX[®] FILM COATED TABLET, 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.

- Taking other medicines

CIFLOX[®] FILM COATED TABLET may cause unwanted effects if used together with other medications, such as tizanidine, antacids, mineral supplements, warfarin, etc. Tell your doctor or pharmacist if you are taking any other medicines.

How to use CIFLOX[®] FILM COATED TABLET

- How much to use

CIFLOX[®] FILM COATED TABLET can be taken range from 250mg to 750mg twice daily or as single dose depending on different conditions. Please consult your doctor or pharmacist for further information.

- When to use it

CIFLOX[®] FILM COATED TABLET should be taken unchewed with fluid independent of mealtimes. CIFLOX[®] FILM COATED TABLET is also recommended to take with an empty stomach to improve absorption. CIFLOX[®] FILM COATED TABLET

should not be taken with dairy products or mineral-fortified fruit-juice. However dietary calcium as part of the meal does not affect ciprofloxacin absorption.

- How long to use it

Usually, CIFLOX[®] FILM COATED TABLET is taken up to 7-14 days (except for acute uncomplicated gonorrhea and cystitis depending on the severity of the illness and on the clinical and bacteriological course). It is essential to continue therapy for at least 3 days after the disappearance of fever or clinical symptoms.

- If you forgot to use it

If you miss a dose of CIFLOX[®] FILM COATED TABLET, take it as soon as possible. If several hours have passed or if it is nearing time for the next dose, do not double the dose to catch up, unless advised by your health care provider. Do not take two doses at once.

- If you take too much (overdose)

Quickly seek medical attention if you think that you or anyone else has taken too much CIFLOX[®] FILM COATED TABLET.

While you are using it

- Things you must do

Follow your doctor's prescription when you are using CIFLOX[®] FILM COATED TABLET.

- Things you must not do

Do not stop taking this medicine or change the dosing regimen without instruction of your doctor. Do not give CIFLOX[®] FILM COATED TABLET to anyone else, even if they have the same condition as you.

- Things to be careful of

Precaution should be taken while taking CIFLOX[®] FILM COATED TABLET especially in children, epileptics, patients who had suffered from previous Central Nervous System-disorders, people who are allergic to ciprofloxacin and patient administered with drugs which are metabolized via liver.

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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 CIFLOX[®] FILM COATED 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 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.

Tendonitis 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 CIFLOX[®] FILM COATED 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 CIFLOX[®] FILM COATED 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 foot and leg or hands and arms. If this happens, stop taking CIFLOX[®] FILM COATED TABLET 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 CIFLOX[®] FILM COATED 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 CIFLOX[®] FILM COATED TABLET and inform your doctor immediately.

Side effects

CIFLOX[®] FILM COATED TABLET may cause some mild side effects such as diarrhoea, dizziness, headache, loss of appetite, nausea, stomach upset and vomiting. Please consult your doctor/pharmacist for further information.

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).

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.

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

Storage and Disposal of CIFLOX[®] FILM COATED TABLET

- Storage

Store at temperature below 30°C. Protect from light and moisture.

- Disposal

If your doctor or pharmacist tells you to stop taking CIFLOX[®] FILM COATED TABLET or the tablet has passed the expiry date, ask them what to do with any that is left over.

Product Description

- What it looks like

CIFLOX[®] FILM COATED TABLET

- 250mg: A white film coated round tablet, one side impressed with “Y” and the other side impressed with score.
- 500mg: A white film coated oblong shape tablet.
- 750mg: A white film coated oblong shape tablet, one side impressed with “YSP” and the other side impressed with “750”.

- Ingredients

- Active ingredient(s)

Ciprofloxacin hydrochloride

- Inactive ingredients

Lactose

Starch

Sodium Starch Glycolate

Magnesium Stearate

Opadry II White

Purified water

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- MAL number:

CIFLOX[®] FILM COATED TABLET

- 250mg: MAL13085048AZ
- 500mg: MAL13085047AZ
- 750mg: MAL13085049AZ

**Manufacturer and Product
Registration Holder**

Y.S.P. Industries (M) Sdn. Bhd.
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13, Kawasan Perindustrian Bandar Baru
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