

CINOLONE FILM COATED TABLET

Ciprofloxacin (250mg)

What is in this leaflet

1. What Cinolone Tablet is used for
2. How Cinolone Tablet works
3. Before you use Cinolone Tablet
4. How to use Cinolone Tablet
5. While you are using it
6. Side effects
7. Storage and disposal of Cinolone Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Cinolone Tablet is used for

It is used to treat infections such as:

- Lung infections (like pneumonia)
- Sinus and ear infections
- Urinary tract infections (bladder, kidney)
- Skin and soft tissue infections
- Bone and joint infections
- Stomach and abdominal infections
- Blood infections (sepsis)
- Infections of the male and female reproductive organs

Cinolone Tablet is also used when:

- The bacteria causing the infection are resistant to other antibiotics, or
- Individual cannot take other antibiotics (for example, due to allergy), or
- Pseudomonas infection is suspected and there are no better alternatives.

How Cinolone Tablet works

The active ingredient of this medicine is ciprofloxacin. Ciprofloxacin belongs in fluoroquinolone antibiotic group that works by killing bacteria causing the infections.

Before you use Cinolone Tablet

- When you must not use it

Do not use Cinolone Tablet if you:-

- are hypersensitive to ciprofloxacin, other quinolone antimicrobial agents, or any of the other ingredients (listed in Product Description).
- are taking tizanidine (medicine used for muscle spasms)

- Before you start to use it

You should check with your doctor before taking this medicine if you:-

- have experienced any serious adverse reaction in the past taking a fluoroquinolone
- have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).

- have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- 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 arthritis, giant cell arthritis, Behcet’s disease, high blood pressure, or known atherosclerosis).
- have history of seizure or other brain and nerve disorders.
- have kidney, or heart problem.
- have glucose-6-phosphate dehydrogenase deficiency (G6PD)
- have muscle weakness
- have a history of tendon problems during previous treatment with quinolone antibiotics

Pregnancy and breastfeeding

You should check with your doctor if you are pregnant or think you may be pregnant, planning to become pregnant or if you are breastfeeding. Cinolone Tablet is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks.

Caution should be taken when breastfeeding as ciprofloxacin can pass into breast milk and may harm your baby. If treatment is needed, your doctor may ask you to stop breastfeeding during and for a short time after treatment.

Children

Cinolone Tablet is not usually given to children or teenagers because it can affect the growth of bones and joints.

However, doctors may prescribe it to children only for very serious infections, such as:

- Lung infections in children with cystic fibrosis
- Complicated urinary tract or kidney infections
- Inhalation anthrax (after exposure)

The doctor will decide if the benefits outweigh the risks before giving this medicine to a child.

- Taking other medicines

There are a few medicines which may interact with Cinolone Tablet. Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket, or health food shop.

You should talk to your doctor or pharmacist if you are taking:-

- theophylline (for breathing problems such as asthma)
- tizanidine (for muscle stiffness or spasms)
- phenytoin (for fits or epilepsy)
- sulfonylureas such as glibenclamide or glyburide (for diabetes)
- warfarin or other blood thinners (to prevent blood clots)
- probenecid (for gout)
- methotrexate (for arthritis or certain cancers)
- metoclopramide (to prevent nausea and vomiting)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or naproxen (for pain and inflammation)
- H₂-receptor blockers such as ranitidine or famotidine (for stomach ulcers or heartburn)
- other antibiotics of the same group (fluoroquinolones)

Some medicines reduce the effect of ciprofloxacin. You may eat or drink these products a few hours before or after taking your dose:

- antacids, medicines, or supplements containing calcium, magnesium, aluminium, or iron
- sucralfate
- dairy products

How to use Cinolone Tablet

- How much to use

The dose given by your doctor may differ from this leaflet.

The dosage needed will depend on the type and severity of your infections and any medical conditions you may have.

The dose may range from 250mg to 750mg.

- When to use it

Take once or twice daily or as directed by your doctor or pharmacist.

Cinolone can be taken with or without food. The tablets should be swallowed whole with a glass of water. It is best taken with an empty stomach because the medicine can be absorbed more quickly.

- How long to use it

Take this medicine for the duration that your doctor recommends. Normally, you will need to take Cinolone Tablet for 7 to 14 days.

You may need to take the tablet for a longer period for some types of infection. It is important for you to continue to take your tablets according to your doctor's advice even if you are feeling better, to make sure the infection is fully cleared.

- If you forget to use it

Do not take a double dose to make up for the missed dose. If it is almost time for your next dose, wait until then to take the medicine and skip 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 or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause feeling sick or vomiting, stomach pain, dizziness, confusion, tiredness, shaking, fits (seizures), trouble passing urine, swelling of the legs or feet, or in rare cases, breathing difficulty or loss of consciousness.

While you are using it

- Things you must do

- Take Cinolone Tablet only with a doctor's prescription.
- Inform all doctors, dentists and pharmacists who treat you that you are using Cinolone Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Cinolone Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

You may experience mental health problems even when taking/using fluoroquinolone antibiotics, including Cinolone 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 Cinolone Tablet and inform your doctor immediately.

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

Drink more water to maintain your body hydration to prevent the formation of highly concentrated urine.

Avoid direct sunlight or tanning lamps. This medicine can make your skin more sensitive to sunlight and cause sunburn.

Inform your doctor immediately if you notice any allergic reaction such as rash, itching, swelling of the face, lips, or throat, or difficulty breathing.

Driving and using machines

This medicine may affect your ability to drive or use machines. If this medicine makes you feel dizzy, light-headed, or less alert, do not drive or use machines and contact your doctor immediately.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Cinolone 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 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 Cinolone 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 Cinolone 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 Cinolone Tablet and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Side Effects

Like all medicines, Cinolone Tablet can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you experience any side effects after taking Cinolone Tablet including:-

- Whole body: headache, abdominal pain, foot pain, pain in extremities (discomfort sensation around arms and legs), injection site reaction (ciprofloxacin administered through injection).
- Cardiovascular system: strong pounding of heartbeat, uncommon or irregular heart rhythm, temporary loss of consciousness, high blood pressure, chest tightness, heart attack, stroke, inflammation of the vein, rapid heart rate, migraine, low blood pressure.
- Nervous system: manic reaction, restlessness, dizziness, lightheadedness, difficulty to sleep, nightmares, hallucinations, hysteria, inflammation, shaking, ataxia (lack of muscle control), fits, fatigue, drowsiness, weakness, malaise, loss of appetite,

phobia, depersonalization, depression, paresthesia (abnormal sensation such as tingling or pricking), abnormality of walking pattern, seizure.

- Gastrointestinal: painful oral mucosa, fungus infection in mouth, swallowing disorder, stomach ulcer with possible perforation and bleeding, jaundice, hepatitis.
- Hemic/Lymphatic: lymph nodes diseases, skin blood vessels leaking.
- Laboratory test: Increase in enzyme amylase and lipase.
- Musculoskeletal: back pain, joint stiffness, achiness, neck or chest pain, gout, serious autoimmune neuromuscular disease, post marketing serious adverse events including deaths and requirement for ventilator support.
- Kidney/Urogenital: kidney inflammation, kidney failure, excessive urination volume, urinary retention, urethral bleeding, vaginal infection in woman, high acid level in blood, breast pain.
- Respiratory: shortness of breath, bleeding from the nose, excessive fluid in lungs, hiccup, cough bleeding, bronchial spasm, blood clots in lungs.
- Skin/Hypersensitivity: allergic reaction, pruritus (itchiness), hives, sensitive to light, flushing, fever, chills, angioedema (swelling of the deeper layers of the skin), oedema (excess fluid accumulates under the skin of face, neck, lips or hand), fungus infection, skin discolouration, erythema nodosum (tender lumps due to inflammation of fat cells under the skin), sweating.
- Sensory: blurred vision, eyes sensitive to light, clarity of vision decrease, diplopia (double vision), eye pain, ringing in the ear, hearing loss, foul taste in the mouth, seeing objects abnormally coloured. In several instances nausea, vomiting, shaking, irritability or strong pounding of heartbeat was observed due to elevated serum level of theophylline side effects as results of drug interaction with ciprofloxacin.
- Children: musculoskeletal side effects disorders has been observed during the clinical trials or post-marketing experience.
- Mental health:
 - 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).

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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

Storage and disposal of Cinolone Tablet

- Storage

Store at or below 30°C and away from excess heat and 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

It is white, round, biconvex film-coated tablet, with **ST** scored on one side.

131

- Ingredient(s)

- Active Ingredient

- Ciprofloxacin

- Inactive Ingredients

- Lactose Hydrate
- Corn Starch
- Dibasic Calcium Phosphate
- Sodium Starch Glycolate
- Magnesium Stearate
- Purified Water
- Alcohol 95%
- Opadry II

- MAL number

MAL10110029AZ

Manufacturer

Taiwan Biotech Co., Ltd.
22, Chieh Shou Road,
Taoyuan, Taiwan R.O.C

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

Date of revision

09/12/2025

Serial number

NPRA(R4/1)231025/00072