

# AXCEL CIPROFLOXACIN TABLET

Ciprofloxacin Hydrochloride (250mg & 500mg)

## What is in this leaflet

1. What Axcel Ciprofloxacin Tablet is used for.
2. How Axcel Ciprofloxacin Tablet works.
3. Before you use Axcel Ciprofloxacin Tablet.
4. How to use Axcel Ciprofloxacin Tablet.
5. While you are using it.
6. Side effects.
7. Storage and disposal of Axcel Ciprofloxacin Tablet.
8. Product description.
9. Manufacturer and product registration holder.
10. Date of revision.

## What Axcel Ciprofloxacin Tablet is used for

Axcel Ciprofloxacin Tablet is used to treat infections caused by ciprofloxacin sensitive pathogens.

## How Axcel Ciprofloxacin Tablet work

Ciprofloxacin is a synthetic antibacterial agent against all Gram-negative and Gram-positive organisms.

## Before you use Axcel Ciprofloxacin Tablet

### -When you must not use it

Do not take Axcel Ciprofloxacin Tablet if:

- You are allergic or hypersensitive to ciprofloxacin or any component of this medication.
- You are pregnant or nursing mother.

### -Before you start to use it

Tell your doctor if:

- You have history of CNS disorders.
- You have impaired liver and renal function.
- You have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- You have experienced a previous episode of aortic dissection (a tear in the aorta wall).

- 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 disorder such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis).
- You have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Thing to be careful of and Side effects).

### -Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Ciprofloxacin Tablet.

## How to use Axcel Ciprofloxacin Tablet

### -How much to use

- Follow recommendations and advices from your doctor or pharmacist.

### -When to use it

Your doctor will decide when it is appropriate for you to take Axcel Ciprofloxacin Tablet according to the type of infection you have.

### -How long to use it

- Follow recommendations and advices from your doctor or pharmacist.

### -If you forget to use it

- Do not double up the dosage as Axcel Ciprofloxacin Tablet may give you unacceptable side effects.

### -If you use too much (overdose)

You must inform your doctor immediately if you have taken too much Axcel Ciprofloxacin Tablet.

## While you are using it

### -Things you must do

- Discuss with your doctor or pharmacist the dos’ and don’ts’ while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Axcel Ciprofloxacin Tablet according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

### -Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

### -Things to be careful of

- Avoid prolonged use with high dosage.
- No driving or operating machinery when feeling drowsy after taking the medicine.
- Avoid direct exposure to excessive sunlight or UV-light.
- If you sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

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

### Prolonged, disabling and potentially irreversible serious side effects:

Fluoroquinolone antibacterial medicines, including Axcel Ciprofloxacin 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.

# AXCEL CIPROFLOXACIN TABLET

Ciprofloxacin Hydrochloride (250mg & 500mg)

Stop taking your fluoroquinolone antibiotic and contact your doctor or pharmacist immediately if you have following of side effects:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your doctor or pharmacist.
- 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.
- Change in your vision, taste, smell, or hearing.

Tell your doctor or pharmacist if you 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 doctor or pharmacist 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 (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 Axcel Ciprofloxacin 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 Axcel Ciprofloxacin Tablet, contact your doctor or pharmacist 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 Axcel Ciprofloxacin Tablet and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

### **Side effects**

Like all medicines, Axcel Ciprofloxacin Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information.

Fluoroquinolone have been reported to cause serious side effects involving tendons, muscles, 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).

Others side effects have been reported are:

- Nausea
- Diarrhea
- Allergic reactions
- High Blood Sugar
- Confusion, Nervous Tension, Abnormal dreams, Depression or Hallucinations (Illusory perception of an object when no object is present)
- Visual disturbance
- Hearing Loss
- Liver failure, Jaundice (yellowing of the skin and whites of the eyes) or Inflammation of liver (non- infective)
- Kidney failure
- Oedema or Sweating
- 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 [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### **Storage and disposal of Axcel Ciprofloxacin Tablet**

#### -Storage

Keep Axcel Ciprofloxacin Tablet out of reach of children.

Store below 30°C. Protect from light.

#### -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

Axcel Ciprofloxacin-250mg Tablet is round shaped, white color film-coated tablet debossed with the Kotra logo on one side and score line on the reverse side.

Axcel Ciprofloxacin-500mg Tablet is white color capsule shaped, film-coated tablet embossed with the word Kotra on one side and score line on the reverse side.

#### -Ingredients

- Active Ingredient (s):

Ciprofloxacin Hydrochloride

- Inactive Ingredients:

Microcrystalline Cellulose  
PH101, Pregelatinized Starch,  
Purified Water, Crospovidone,  
Aerosil 200M, Magnesium  
Stearate and Opadry White

#### -MAL Number

Axcel Ciprofloxacin-250mg Tablet:  
MAL13115208AZ

Axcel Ciprofloxacin-500mg Tablet:  
MAL13115209AZ

# AXCEL CIPROFLOXACIN TABLET

*Ciprofloxacin Hydrochloride (250mg & 500mg)*

---

**Manufacturer and product  
registration holder**

Kotra Pharma (M) Sdn Bhd  
No. 1, 2 & 3, Jalan TTC 12,  
Cheng Industrial Estate,  
75250 Melaka, Malaysia.

**Date of revision**

23/05/24

**Serial number**

NPRA(R2/1)201028/546