INSERT AKILEN
(05 FEB '21) - Exp. Singapore

Rx

PRESCRIPTION DRUG

AKILEN®
Ofloxacin
Film-coated tablet

Each Film-coated tablet contains:
Ofloxacin ..... 200 mg

PHARMACOLOGY

AKILEN® contains ofloxacin, a fluoroquinolone antibacterial agent with bactericidal activity against a wide range of Gram-negative and Gram-positive organisms and some anaerobic bacteria.

AKILEN® has a bactericidal effect by inhibiting the A subunit of bacterial DNA gyrase, an enzyme responsible for the supercoiling of DNA. This interaction leads to inhibition of bacterial DNA replication.

The Gram-negative bacteria susceptible to **AKILEN®** are as follows:

E. coli, Klebsiella, Enterobacter, Proteus, Providencia, Citrobacter, Serratia, Salmonella, Shigella, *Yersinia enterocolitica, Vibrio species, Legionella pneumophila, Campylobacter jejuni, Pseudomonas aeruginosa* including strains that are resistant to other antibacterial agents.

The Gram-positive bacteria susceptible to **AKILEN®** are as follows:

Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus saprophyticus, Streptococcus pneumoniae, Streptococcus faecalis, Mycobacterium tuberculosis, certain atypical Mycobacteria and *Chlamydia trachomatis* are also susceptible to **AKILEN®**.

AKILEN® administered orally has better pharmacokinetics properties than ciprofloxacin, including greater bioavailability and a longer half-life.

Oral bioavailability of **AKILEN®** is about 95%, plasma protein binding is about 8% and half-life between 5 - 7 hours.

INDICATIONS

AKILEN® is indicated for severe infections in:
- Urinary-tract infections.
- Gonococcal and non gonococcal urethritis, gonococcal and non gonococcal cervicitis.
- Lower respiratory-tract infections.
- Skin and soft tissue infections.

CONTRA-INDICATIONS

1. Hypersensitivity to Ofloxacin and quinolone derivatives.
2. Pregnant and nursing women.
3. Prepubertal children.

DRUG INTERACTIONS

Drugs known to prolong QT interval

Ofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics).

WARNINGS AND PRECAUTIONS

1. If hypersensitivity reactions and shock-like symptoms occur, discontinue the drug.
2. Use with caution in patients with reduced renal function, and adjust doses according to the severity of renal dysfunction. Elderly patients may require a reduction in dosage, since they may have reduced creatinine clearance.
3. It should be given with caution during fertile age.
4. Concominant administration with antacid containing aluminium or magnesium hydroxide may reduce absorption of Ofloxacin. Therefore, it should be administered 1 to 2 hours before or after Ofloxacin.
5. Cardiac Disorders
   Caution should be taken when using fluoroquinolones, including ofloxacin, in patients with known risk factors for prolongation of the QT interval such as, for example:
   - congenital long QT syndrome.
   - concomitant use of drugs that are known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics)
   - uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia)
   - elderly
   - cardiac disease (e.g. heart failure, myocardial infarction, bradycardia)
6. Exacerbation of Myasthenia Gravis
   Fluoroquinolones, including ofloxacin, have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Post-marketing serious adverse events, including deaths and requirement for ventilatory support, have been associated with fluoroquinolone use in persons with myasthenia gravis. Avoid ofloxacin in patients with a known history of myasthenia gravis.
7. Peripheral Neuropathy
   Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including **AKILEN®**. Symptoms may occur soon after initiation of **AKILEN®** and may be irreversible. **AKILEN®** should be discontinued immediately if the patient experiences symptoms of peripheral neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.
8. Vision Disorders
   If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.
9. Disabling and Potentially Irreversible Serious Adverse Reactions
   Fluoroquinolones, including **AKILEN®**, have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). Patients of any age or without pre-existing risk factors have experienced these adverse reactions.
   Discontinue **AKILEN®** immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including **AKILEN®**, in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.
10. Psychiatric Adverse Reactions
    Fluoroquinolones, including **AKILEN®**, have been associated with an increased risk of psychiatric adverse reactions, including: toxic psychosis, hallucinations, or paranoia; depression or suicidal thoughts or acts; anxiety, agitation, or nervousness; confusion, delirium, disorientation, or disturbances in attention; insomnia or nightmares; memory impairment. These adverse reactions may occur following the first dose. If these reactions occur in patients receiving **AKILEN®**, discontinue **AKILEN®** immediately and institute appropriate measures.
11. Blood Glucose Disturbances
    As with all fluoroquinolones, disturbances in blood glucose, including both hypoglycaemia and hyperglycaemia have been reported with **AKILEN®**. In **AKILEN®**-treated patients, dysglycaemia occured predominantly in elderly diabetic patients receiving concomitant treatment with an oral hypoglycaemic agent (for example, sulfonylurea) or with insulin. Severe cases of hypoglycaemia resulting in coma or death have been reported. In diabetic patients, careful monitoring of blood glucose is recommended. If a hypoglycaemic reaction occurs, discontinue **AKILEN®** and initiate appropriate therapy immediately.
12. Aortic aneurysm or dissection and heart valve regurgitation/incompetence
    Epidemiologic studies report an increased risk of aortic aneurysm and dissection, particularly in elderly patients, and of aortic and mitral valve regurgitation after intake of fluoroquinolones. Cases of aortic aneurysm and dissection, sometimes complicated by rupture (including fatal ones), and of regurgitation/incompetence of any of the heart valves have been reported in patients receiving fluoroquinolones.
    Therefore, fluoroquinolones should only be used after a careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease or congenital heart valve disease, or in patients diagnosed with pre-existing aortic aneurysm and/or dissection or heart valve disease, or in presence of other risk factors or conditions predisposing
    - for both aortic aneurysm and dissection and heart valve regurgitation/incompetence (e.g. connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome, Turner syndrome, Behçet's disease, hypertension, rheumatoid arthritis) or additionally,
    - for aortic aneurysm and dissection (e.g. vascular disorders such as Takayasu arteritis or giant cell arteritis, or known atherosclerosis, or Sjögren's syndrome) or additionally
    - for heart valve regurgitation / incompetence (e.g. infective endocarditis),

    The risk of aortic aneurysm and dissection, and their rupture may also be increased in patients treated concurrently with systemic corticosteroids.
    In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department.
    Patients should be advised to seek immediate medical attention in case of acute dyspnoea, new onset of heart palpitations, or development of oedema of the abdomen or lower extremities.

OVERDOSE

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

ADVERSE REACTIONS

Ofloxacin, as fluoroquinolones in general has been well tolerated and adverse reactions seldom were severe enough to require discontinuation of therapy.

Adverse reactions affect the gastro-intestinal tract and the central nervous system most frequently e.g. nausea, headache, dizziness, and insomnia.

Other adverse effects of the gastro-intestinal tract include vomiting, diarrhea, decreased appetite, abdominal pain and dry mouth.

Hypersensitivity reactions: skin rash and pruritus.

Laboratory abnormalities also occur infrequently and are minor and reversible. These include elevations in BUN, serum creatinine levels, SGOT, SGPT, alkaline phosphate, gamma-GT, total bilirubin, decrease in leucocytes, erythrocytes, Hb and platelet counts, and increase in eosinophil.

Possibility of Tendon Disorders, eg. Tendon Rupture.

Nervous system disorders (frequency not known): Peripheral neuropathy (that may be irreversible) and polyneuropathy.

Cardiac disorders

Not known: ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged.

Exacerbation of Myasthenia Gravis

INFORMATION FOR PATIENTS

Patients should be advised to:
Inform their physician of any history of myasthenia gravis and to notify their physician if they experience any symptoms of muscle weakness, including respiratory difficulties.

DOSAGES

Adults:
- Urinary-tract infections, 200 - 400 mg daily preferably in the morning, increased if necessary in urinary-tract infections to 400 mg twice daily.
- Lower respiratory-tract infections, 400 mg daily preferably in the morning, increased if necessary to 400 mg twice daily.
- Skin and soft-tissue infections, 400 mg twice daily .
- Uncomplicated gonorrhoeae, 400 mg as a single dose.
- Non-gonococcal urethritis and cervicitis, 400 mg daily in single or divided doses.

PRESENTATIONS

Box of 3 strips @ 10 tablets.
Reg. No.: SIN11377P

STORAGE

Store below 30°C

Manufactured by:
PT SANBE FARMA
Jalan Industri I No.9 RT.01 RW.08, Kelurahan Utama,
Kecamatan Cimahi Selatan, Kota Cimahi - Indonesia

* BF 148 - ESG6

Country:	Packaging:	Dimension:	Material:	Color:	Scale:
Singapore	Brochure	140 x 190 mm (double side printing)	HVS paper 60 g	BLACK	100%