[싱가포르]
푸가신정 설명서

Size : 110 × 300 (mm)

Quinolone Antibacterial Agent

FUGACIN Tablets (Ofloxacin)

FUGACIN is a broad spectrum antibacterial agent of quinolone derivative.
It shows potent antibacterial activities against gram-negative bacteria such as Escherichia coli, Klebsiella pneumonia, Serratia sp., Proteus sp., Pseudomonas aeruginosa, and Hemophilus influenzae and moreover gram-positive bacteria such as staphylococcus sp., hemolytic streptococcus enterococci, and anaerobic Peptostreptococci. After administration, it is rapidly transferred to each tissue in high concentrations and since it is mostly excreted in the urine almost unchanged, it also active against urinary tract infections.

[COMPOSITION]
Each tablet contains 200mg of Ofloxacin

[INDICATIONS]
The following infections caused by ofloxacin-susceptible Staphylococcus sp., Streptococcus pyogenes, hemolytic streptococci, enterococci, Streptococcus pneumoniae, peptostreptococcus sp., Escherichia coli, Citrobacter sp., Shigella sp., Klebsiella pneumoniae, Enterobacter sp., Serratia sp., Proteus sp., Pseudomonas aeruginosa, Haemophilus influenzae, Acinetobacter sp., and Campylobacter sp.

- Folliculitis, furuncle, furunculosis, carbuncle, erysipelas, phlegmon, lymphangitis(lymphadenitis)
- felon, subcutaneous abscess, spiradenitis, acne conglobata, infectious atheroma, perianalabscess
- Mastadenitis, superficial secondary infections after traumas, burns, surgery traumas
- Pharyngolaryngitis, acute bronchitis, tonsillitis, chronic bronchitis, diffuse panbroncholitis,bronchiectasis with infection, secondary infections of chronic respiratory diseases,pneumonia
- Pyelonephritis, cystitis, prostatitis, epididymitis, gonococcal urethritis, non-gonococcalurethritis
- cholecystitis, cholangitis, bacillary dysentery, enteritis
- Intrauterine infection, adnexitis, bartholinitis
- Blepharitis, hordeolum, dacryocystitis, tarsadentitis, keratohelcosis
- Otitis media, sinusitis

[DOSAGE AND ADMINISTRATION]
FUGACIN is generally given to adults orally in a daily dose of 1.5-3 tablets (300-600mg) divided into 2 to 3 times.
Dosage may be adjusted according to causative organisms and severity of symptoms.
Overdose: In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

[PRECAUTIONS]
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 FUGACIN. Symptoms may occur soon after initiation of FUGACIN and may be irreversible. FUGACIN 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.

Vision disorders

If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately

1.Contraindication
Patients with a history of hypersensitivity to ofloxacin.
2.Careful administration
1)Patients with severe renal disorders
2)Patients with or with a history of convulsive diseases such as epilepsy.
3)Patients with a history of hypersensitivity to quinolones.
4)The elderly patients
3.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)

4.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. There is a risk of tendon rupture with use of fluoroquinolone antibiotics
5.Adverse reactions
1)Shock: Shock-like symptoms rarely occur. In such a case, observe the patients carefully. If suchsymptoms as feeling unwell, sweating, dyspnea, or hypotension are observed, discontinue the medication and take appropriate treatments.
2)Hypersensitivity: Rarely anaphylaxis (erythema, chill, dyspnea), edema, urticaria, heat,occasionally eruption, pruritus may occur. If such signs develop, discontinue the medication.
3)Renal: Kidney failure elevation of BUN and serum creatinine may infrequently occur.
4)Hepatic: Icterus elevation of S-GOT, S-GPT, AL-P, γ -GPT or total bilirubin may occur.
5)Digestive: Rarely, a serious form of colitis accompanied by bloody stools, such as pseudomembranous colitis may occur. If abdominal pain and recurrent diarrhea occur, take appropriate measures such as immediate discontinuation of the drug treatment. Nausea/vomiting, discomfort in stomach/abdomen, diarrhea/loose stool, anorexia, stomachache /abdominal pain or heartburn may infrequently occur, and thirst or stomatitis may appear rarely.
6)Hematologic: Rarely anemia, leukopenia, erythropenia, oligochromemia decrease in hematocrit,thrombo lytopenia, eosinophilia may occur. If abnormality is observed, appropriate treatment including discontinuation of therapy should be initiated.
7) Psychoneurologic: Insomnia, dizziness, or headache may infrequently occur, and convulsion, tremor numbness dysopia, sonitus, fallacia, drowsiness, may appear rarely.
8) Cardiac disorders: Not known: ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged.
9)Others:
1.Hypoglycemia has been reported in other new quinolones since this product should be administered cautiously.
2.Malaise, pyrexia, palmus may occur rarely.
3.Exacerbation of myasthenia gravis
10)Nervous system disorders (frequency not known): Peripheral neuropathy (that may be irreversible) and polyneuropathy
6.Drug Interactions
1)It has been reported that the concomitant use of other quinolones (enoxacin, etc.) withnonsteroidal anti-inflammatory phenylacetic/propionic acid derivatives, such as fenbufen, etc.
2)Antacid containing aluminum or magnesium may interfere with the absorption of ofloxacin,resulting in attenuation of the efficacy of ofloxacin.
3)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)
7.Use during pregnancy or lactation

1)Safety during pregnancy has not been established; therefore FUGACIN should not be administered to patients who are or may become pregnant.
2)Since FUGACIN transfers to human milk, it is recommended to refrain from lactation during the administration of this drug.
8.Pediatric use
Since safety in children has not been established, FUGACIN should not be administered to children.
9.Geriatric use
When used in elderly patients in whom kidney function is usually decreased, the serum half-life of administered this product may be extended and high serum levels may persist for a long time; therefore keep the recommended dosage and administration.
10.Others
Animal studies have shown that ofloxacin can produce arthropathy in immature dogs and rats.

[Warnings and Precautions]
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.

Disabling and potentially irreversible serious adverse reactions
Fluoroquinolones, including Qupron tablet, have been associated with disabling and otentially 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 Qupron tablet immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including [Product Name], in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.

Psychiatric Adverse Reactions
Fluoroquinolones, including Qupron tablet, 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 Qupron tablet, discontinue Qupron tablet immediately and institute appropriate measures.

Blood Glucose Disturbances
As with all fluoroquinolones, disturbances in blood glucose, including both hypoglycaemia and hyperglycaemia have been reported with [Product Name]. In [Product Name]-treated patients, dysglycaemia occurred 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 [Product Name] and initiate appropriate therapy Immediately.

[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.

[STORAGE] Store in a well-closed container at room temperature

[EXPIRY] 36 Months

[HOW SUPPLIED] 10, 100, 500, 1000 tablets. Not all presentations may be available locally.

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