[싱가포르]
큐프론정 설명서

Size : 150 x 255 (mm)

Bactericidal Antibacterial Agents

QUPRON Tablets 250mg 500mg

Ciprofloxacin HCl

【COMPOSITION】
Each tablet contains
Ciprofloxacin HCl ····· 291.0mg or 582.0mg
(As 250mg (potency) or 500mg (potency) of Ciprofloxacin)

【INDICATIONS】
1. Susceptible organisms : E. coli, Shigella, Salmonella, Citrobacter, Klebsiella, Enterobacter, Serratia, hafnia, proteus(Indole positive & negative). Pseudomonas, Neisseria, Acinetobacter, Streptococcus, Chlamydia, Staphylococcus,Corynebacterium, Bacteroides, Clostridium

2. Indications
Respiratory infections, infections of oral cavity, teeth and jaw, infections of ear, nose and throat, infections of kidney or urinary passages, genital infections containing gonorrhea, gastrointestinal infections, infection and wound of soft tissue, infections of bone and joint, infections in gynecological and obstetric field, septicemia, cerebromeningitis, peritonitis, ophthalmologic infections and infections in bile secretory duct.

【DOSAGE AND ADMINISTRATION】
1. Usually for adults, administer 250~500mg at meal intervals twice a day. In severe mixed infections, administer up to750mg twice a day. In acute infections, usually treat for 5 to 10 days. After disappearance of symptoms, furtheradministration is required at least for 3 days.

2. In patients with severe renal disorder, it should be administered according to the following dosage and administration.

Creatinine Clearance (ml/min)	Dosage and Administration
>50	Administer by general dosage
30~50	250~500mg twice a day
5~29	250~500mg every 18 hours
Patients on hemodialysis or peritoneal dialysis	250~500mg once a day (after dialysis)

When only the concentration of serum creatinine clearance is known, the patient's creatinine clearance can be estimated by using the following formulas:

$$\text{Male: Creatinine Clearance (ml/min)} = \frac{\text{Weight (in kg) x (140 - age)}}{\text{72 x serum creatinine (mg/dl)}}$$

Female: Creatinine Clearance (ml/min) = 0.85 x male's Creatinine Clearance

In patient with severe cardiac failure and infections, 750mg can be administered once, but careful monitoring is required and the ciprofloxacin concentration should be periodically estimated. At that time, the peak serum concentration (obtained 1~2 hours after administration) should range from 2~4μg/ml.

3. Dosage may be adjusted according to causative organisms and severity of symptom.

【PRECAUTIONS】
1. Contraindications
1) Patients previously found hypersensitive to it.
2) Pregnancy and nursing woman
3) Children and infants
4) Patients with hepatic disorder

2. Careful Administrations
1) Patients with severe renal disorder
2) Use after confirming the appropriate anti-convulsion therapy to patients whom cerebral epileptic seizure has occurred in.
3) Elderly patients
4) Patients with cerebral blood flow disturbance.
5) Patients with damaged venous system.
6) Cardiac disorders
(1) Caution should be taken when using fluoroquinolones, including ciprofloxacin, in patients with known risk factors for prolongation of the QT interval such as, for example :
(2) Congenital long QT syndrome
(3) Concomitant use of drugs that are known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics)
(4) Uncorrected electrolyte imbalance (e.g. Hypokalaemia, hypomagnesaemia)
(5) Elderly
(6) Cardiac disease (e.g. Heart failure, myocardial infarction, bradycardia)
(7) Vision disorders
If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately

3. Adverse Effects
1) Shock : Since shock may rarely occur, close observation should be made. If symptoms occur, the drug should be discontinued and appropriate measures taken
2) Skin : Since muco cutaneous ocular syndrome (Stevens-Johnson syndrome) or photosensitivity may rarely occur, close observation should be made. If these symptoms occur, the drug should be discontinued.
3) Hypersensitivity : Rarely pharynx edema, facial edema, pruritus, pyrexia or occasionally rashes may occur. If these symptoms occur, the drug should be discontinued.
4) Renal : Rarely acute renal insufficiency and occasionally elevation of BUN-or creatinine may occur.
5) Hepatic : Since rarely jaundice or occasionally elevation of GOT, GPT and AL-P may occur, close observation should be made. If these symptoms occur, the drug should be discontinued and appropriate measures taken.
6) Hematologic : Since occasionally leukopenia, thrombocytopenia, eosinophilia, or rarely erythropenia, decrease of hemoglobin or hematocrit level may occur, close observation, should be made. If these symptoms occur, the drug should be discontinued.
7) Gastrointestinal : Rarely severe enterocolitis with hemafecia such as pseudomembranous enterocolitis may occur. If abdominal pain and frequent diarrhea occur, appropriate measures such as immediate discontinuation of the drug should be taken. Occasionally anorexia, diarrhea, stomach upset, nausea, vomiting, abdominal pain, abdominal fullness or rarely stomatitis may occur.
8) Psychoneurologic : Occasionally headache, vertigo or rarely feeding of tongue paralysis, drowsiness, tremor, visual disturbance may occur.
9) Muscle : Since striped myolysis accompanied with sudden deterioration of renal function characterized by myalgia, elevation of CPK, elevation of myoglobin in blood or urine may occur, the drug should be administered cautiously.

10) Respiratory : Since interstitial pneumonia accompanied with fever, cough, dyspnea, abdominal chest X-ray, eosinophilia, etc. may occur in case that such symptoms occur, further administration should be discontinued and appropriate measures such as administration of corticosteroids, etc. should be taken.
11) Cardiac disorders : Not known, ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged
12) Other
(1) Rarely arthralgia may occur.
(2) Since hypoglycemia has been reported in other new quinolones (elderly patients, especially it is prone to occur in patients with renal disorder), this drug should be cautiously administered.

4. Drug Interactions
1) It has been reported that combination with theophylline elevated serum theophylline concentration. In case of combination with theophylline, it should be cautiously administered (reduction of theophylline quantity. etc)
2) Since convulsion rarely occur by combination with ketoprofen, it should not be combined. Since convulsion may occur by combination with other phenylacetate or propionate non-steroidal anti-inflammatory analgesics, it should be administered with caution.
3) Since iron and antacid containing aluminum or magnesium may interfere with the absorption of this drug,resulting in allenuation of the efficacy, it should be administered with caution.
4) Serum creatinine concentration may increase with combination of cyclosporine.
5) Ciprofloxacin, 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, anti psychotics)

5. Use during Pregnancy and Lactation
Because safety in use during pregnancy and lactation is not established, it is desirable that this drug is not given to them.

6. Use in Children
Because safety in children is not established, it is desirable that this drug is not given to them.

7. Others
1) Since it has been reported in foreign countries that tendon disorders such as achillobursitis, tendon rapture,etc. Rarely occur, close clinical observation is required and if abnormality is acknowledged, further administration should be discontinued and appropriate measures taken.
2) Animal studies have shown that this drug can produce dysarthrosis in immature dogs and rats.
3) It has been reported that crystalluria appeared by large dosage (750mg/more than once).

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

【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, Behcet'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 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 Qupron tablet immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including [QUPRON], 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 [QUPRON]. In [QUPRON]-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 [QUPRON] and initiate appropriate therapy Immediately.

【STORAGE】
Store in a well-closed container

【HOW SUPPLIED】
10, 60, 100, 500 tablets. Not all presentations may be available locally.

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