

POLI-CIFLOXIN 250

Composition:	Each tablet contains Ciprofloxacin HCl monohydrate equivalent to Ciprofloxacin 250 mg
Properties:	Ciprofloxacin is a fluoroquinone bactericidal and acts by inhibiting the A subunit of DNA gyrase (topoisomerase) which is essential in the reproduction of bacterial DNA. It has a wide spectrum of activity including Enterobacteriaceae, <i>Pseudomonas aeruginosa</i> , <i>Haemophilus</i> , and <i>Neisseria</i> spp. and also against staphylococci and some other Gram-positive bacteria.
Indications:	For treatment of infections caused by sensitive to Ciprofloxacin gram positive and gram negative pathogens in respiratory tract, ear, sinuses, kidneys, urinary tract and etc.
Dosage:	The usual dose is 250-500 mg twice daily or as prescribed by a physician. A single dose of 250 mg for the treatment of gonorrhoea.
Warnings and precautions:	<p><u>Cardiac disorders</u></p> <p>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:</p> <ul style="list-style-type: none">- 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) <p><u>Peripheral Neuropathy</u></p> <p>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 Poli-Cifloxin 250. Symptoms may occur soon after initiation of Poli-Cifloxin 250 and may be irreversible. Poli-Cifloxin 250 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.</p> <p><u>Vision disorders</u></p> <p>If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.</p> <p><u>Disabling and potentially irreversible serious adverse reactions</u></p> <p>Fluoroquinolones, including Poli-Cifloxin 250, 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 Poli-Cifloxin 250 immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including Poli-Cifloxin 250, in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.</p> <p><u>Aortic aneurysm or dissection and heart valve regurgitation/incompetence</u></p> <p>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.</p> <p>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.</p>

- 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.

Psychiatric Adverse Reactions

Fluoroquinolones, including Poli-Cifloxin 250, 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 Poli-Cifloxin 250, discontinue Poli-Cifloxin 250 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 Poli-Cifloxin 250. In Poli-Cifloxin 250-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 Poli-Cifloxin 250 and initiate appropriate therapy immediately.

Adverse effects:	<p>Mild gastro-intestinal side effects have been reported.</p> <p>Allergic reactions have occurred rarely. As with other quinolone antibacterial agents reversible arthralgia has sometimes occurred and joint erosions have been documented in immature animals. Tendon damage has been reported.</p> <p><u>Cardiac disorders</u></p> <p>Not known: ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation). ECG QT prolonged.</p> <p><u>Nervous system disorders</u> (frequency not known): Peripheral neuropathy (that may be irreversible) and polyneuropathy.</p>
Contraindications:	<p>Hypersensitivity to ciprofloxacin or other quinolones.</p> <p>Children, adolescents, pregnancy and lactation.</p>
Drug Interactions:	<p>Ciprofloxacin may interact with various compounds including antacids, iron preparations, theophylline, and warfarin. Recommend that ciprofloxacin should not be administered by mouth within 4 hrs. of taking preparations containing magnesium, aluminium, or iron salts.</p> <p><u>Drugs known to prolong QT interval</u></p> <p>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, antipsychotics).</p>
Use in pregnancy:	Should not be used in pregnant women, or breast-feeding mothers.
Overdose:	In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.
Storage:	Do not store above 30°C and protect from light.
Manufacturer:	POLIPHARM CO., LTD. Samut prakan Thailand.
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