MINACID

Nalidixic Acid Oral Suspension BP

Composition: Each 5 ml contains:
Nalidixic Acid BP 300 mg
Flavored syrup base q.s.
Color: Approved color used.

Indications: Nalidixic acid is used to treat urinary tract infections. It is highly effective against Gram-negative bacilli such as *E. coli* and *Proteus*.

Warnings: Central Nervous System (CNS) effects, including seizures, increased intracranial pressure, and toxic psychosis, have been reported with nalidixic acid therapy. Seizures have been reported with other drugs in this class. Quinolones can also cause CNS stimulation, which may lead to tremors, nervousness, dizziness, confusion, and hallucinations. Therefore, nalidixic acid should be used with caution in patients with known or suspected CNS disorders—such as cerebral arteriosclerosis or epilepsy—or other factors predisposing them to seizures. If these reactions occur in patients receiving nalidixic acid, the drug should be discontinued and appropriate measures instituted. Severe and occasionally fatal hypersensitivity (anaphylactoid) reactions—some occurring after the first dose—have been reported in patients receiving quinolone therapy. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, facial or pharyngeal edema, dyspnea, urticaria, and pruritus. Only a few patients had a history of hypersensitivity reactions. Severe anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management (including intubation) should be administered as indicated. Nalidixic acid and other members of the quinolone class of drugs have been shown to cause arthropathy in young animals. *Clostridium difficile* -associated diarrhea (CDAD) has been reported with the use of almost all antibacterial agents, including nalidixic acid, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to the overgrowth of *C. difficile*. *C. difficile* produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD should be considered in all patients presenting with diarrhea following antibiotic use. A thorough patient history is necessary, as CDAD has been reported to occur up to two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment for *C. difficile*, and surgical evaluation should be initiated as clinically indicated.

Peripheral neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons—resulting in paresthesia, hypoesthesia, dysesthesia, and weakness—have been reported in patients receiving quinolones, including nalidixic acid. Nalidixic acid should be discontinued if the patient exhibits symptoms of neuropathy (such as pain, burning, tingling, numbness, and/or weakness) or is found to have deficits in light touch, pain, temperature, position sense, vibration sense, and/or motor strength, in order to prevent the development of an irreversible condition.

Tendon effects: Ruptures of the shoulder, hand, Achilles, or other tendons requiring surgical repair or resulting in prolonged disability have been reported in patients receiving quinolones, including nalidixic acid. Post-marketing surveillance reports indicate that this risk may increase in patients receiving concomitant corticosteroids, especially the elderly. Nalidixic acid should be discontinued if the patient experiences tendon pain, inflammation, or rupture. Patients should rest and refrain from exercise until a diagnosis of tendinitis or tendon rupture has been ruled out. Tendon rupture can occur during or after treatment with quinolones, including nalidixic acid.

Precautions: Complete blood counts and renal and hepatic function tests should be performed periodically if treatment continues for more than two weeks. Masagram should be used with caution in patients with liver disease, epilepsy, or severe cerebral arteriosclerosis. While caution should be exercised in patients with severe renal impairment, therapeutic concentrations of Masagram in the urine—without increased toxicity due to drug accumulation in the blood—have been observed in patients receiving the full dosage with creatinine clearance rates as low as 2 mL/minute to 8 mL/minute. Moderate to severe phototoxicity reactions have been observed in patients exposed to direct sunlight while taking Masagram or other drugs in this class. Excessive sunlight exposure should be avoided. Therapy should be discontinued if phototoxicity occurs.

Caution: Use with caution in the presence of liver disease, severe renal impairment, or respiratory depression. Do not use in premature infants or babies under 3 months of age. Avoid unnecessary exposure to sunlight during treatment with this medication.

Dosage: As directed by the physician.
Storage: Store below 30°C in a cool, dry place. Protect from light.
SHAKE BEFORE USE.
Presentation: 60ml bottle.
Keep medicines out of the reach of children.

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