AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
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LEAFLET

AGONAL

(Nalidixic Acid Tablets BP 500 mg)

Composition :

Each uncoated tablet contains:

Nalidixic Acid BP	500 mg
Excipients	q.s.

Pharmacological Action :

Nalidixic acid is bacterial to most of the common gram-negative bacteria that cause urinary tract infections. It appears to act by inhibiting deoxyribonucleic acid synthesis. Brumfitt and Pursell (1971) reported that 99% of strains of E. coli, 98% of Proteus mirabilis and 75 to 97% of other Proteus species, 92% of Klebsiella-Enterobacter, and 80% of other coliform bacteria are sensitive to the medicine. Pseudomonas species are resistant. Some strains of Salmonella and Shigella are also sensitive. Acquired resistance to the medicine occurs. The effectiveness against indolepositive Proteus is especially important.

Approximately 96% of orally administered nalidixic acid is absorbed. Plasma concentrations of 20 to 50 µg/mL may be achieved, but the acid is 93 to 97% bound to plasma protein. In the body some nalidixic acid is converted to an active hydroxynalidixic acid, and both are excreted into the urine. Most of the medicine is conjugated in the liver. The plasma half-life is normally about 8 hours, but it may be as long as 21 hours in the presence of renal failure. Urinary concentrations usually range from 50 to 100 µg per mL.

Whether nalidixic acid can effectively penetrate the renal medulla and be of direct value in the treatment of pyelonephritis is uncertain.

Indications:

Nalidixic acid is used in the treatment of urinary-tract infections due to gram-negative micro-organisms other than Pseudomonas sp. It has been used in acute and chronic infections and may be effective in urinary infections which have not responded to treatment with antibiotics or sulphonamides. Its antibacterial activity does not appear to be influenced by the urinary pH.

Conta-Indications:

Nalidixic acid should be given with care to patients with damage of the central nervous system, to patients subject to convulsions, and to those with impaired renal or hepatic function. Nalidixic acid may increase respiratory depression in patients with respiratory insufficiency. It should

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not be given to babies less than one month old or to women in the first trimester of pregnancy. Exposure to strong sunlight should be avoided during treatment.

Dosage & Direction for use:

The usual adult dose is 4 g daily in 4 divided doses for at least 7 days in acute infections. If therapy is prolonged, for instance in the treatment of chronic or persistent infections, the dose may be reduced to 2 g daily. Children may be given 55 to 60 mg per kg body-weight daily in 2 to 4 divided doses.

Side effects & special precaution :

Nausea, vomiting, and abdominal pain may occur. Allergic reactions such as pruritis, urticaria, various rashes, photosensitivity, eosinophilia, and fever occasionally occur, and cholestasis, thrombocytopenia, leukopenia, and haemolytic anaemia rarely occur. Liver function tests and blood-cell counts are advisable if treatment lasts longer than 2 weeks. Effects on the central nervous system, such as headache, drowsiness, malaise, vertigo, visual disturbances, and asthenia are experienced infrequently. Diarrhoea, gastro-intestinal bleeding, muscular weakness, myalgia and arthralgia may also occur. The presence of the medicine results in false-positive responses in some urine glucose tests. Nitrofurantoin interferes with the therapeutic action of nalidixic acid.

Known symptoms of overdosage and particulars of its treatment:

Convulsions have followed high or excessive doses in patients with cerebral vascular insufficiency, Parkinsonism or epilepsy, or in normal children given excessive doses, perhaps as the result of intracranial hypertension. In these cases the dose must be reduced or the medicine withdrawn.

Storage:

Store under normal storage conditions (15°C to 30°C).
Protect from light.
Keep all medicines out of reach of children.

Presentation :

Blister Pack of 10 X 10 Tablets, 100 X 10 Tablets,
Jar pack of 1000 Tablets.

Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl.
Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.