Brand Name : AGONAL TABLETS **Generic Name :** Nalidixic Acid Tablets BP 500 mg	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGONAL TABLETS (Nalidixic Acid Tablets BP 500 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Nalidixic Acid BP 500 mg

3. Pharmaceutical form:

White elongated uncoated tablet having a breakline on one side and other side is plain of each tablet.

4. Clinical particulars:

Nalidixic Acid

4.1 Therapeutic indications

Nalidixic acid is a quinolone antibacterial agent for oral administration. Nalidixic acid has marked antibacterial activity against gram-negative bacteria including Enterobacter species, Escherichia coli, Morganella Morganii; Proteus Mirabilis, Proteus vulgaris, and Providencia rettgeri.

Mechanism of action
Evidence exists for Nalidixic acid that its active metabolite, hydroxynalidixic acid, binds strongly, but reversibly, to DNA, interfering with synthesis of RNA and, consequently, with protein synthesis.

Absorption
Following oral administration, nalidixic acid is rapidly absorbed from the gastrointestinal tract. Bioavailability is approximately 96%. Absorption may be delayed if taken with antacids.

Metabolism

Hepatic. 30% of administered dose is metabolized to the active metabolite, hydroxynalidixic acid. Rapid conjugation of parent drug and active metabolite to inactive metabolites. Metabolism may vary widely among individuals. In the urine, hydroxynalidixic acid represents 80 to 85% of the antibacterial activity.

Hover over products below to view reaction partners

- Nalidixic acid
  - Hydroxynalidixic acid

Route of elimination

Following oral administration, NegGram is rapidly absorbed from the gastrointestinal tract, partially metabolized in the liver, and rapidly excreted through the kidneys. Approximately four percent of NegGram is excreted in the feces.

Half-life

1.1 to 2.5 hours in healthy adult patients, and up to 21 hours in patients with impaired renal function.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Nalidixic acid is a quinolone antibacterial agent for oral administration. Nalidixic acid has marked antibacterial activity against gram-negative bacteria including *Enterobacter* species, *Escherichia coli*, *Morganella Morganii*; *Proteus Mirabilis*, *Proteus vulgaris*, and *Providencia rettgeri*. *Pseudomonas* species are generally resistant to the drug. Nalidixic acid is bactericidal and is effective over the entire urinary pH range. Conventional chromosomal resistance to nalidixic acid taken in full dosage has been reported to emerge in approximately 2 to 14 percent of patients during treatment; however, bacterial resistance to nalidixic acid has not been shown to be transferable via R factor. Nalidixic acid is active against most gram-negative organisms that cause urinary tract infections. Nalidixic acid is a monocarboxylic acid comprising 1,8-naphthyridin-4-one substituted by carboxylic acid, ethyl and methyl groups at positions 3, 1, and 7, respectively.

5.2 Pharmacokinetic properties

Nalidixic acid and related antibiotics inhibit a subunit of DNA gyrase and topoisomerase IV and induce formation of cleavage complexes. It also inhibits the nicking-closing activity on the subunit of DNA gyrase that releases the positive binding stress on the supercoiled DNA.
Elimination half-life: 6-7 hours, significantly lon...
Protein binding: 90%

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Micro crystalline cellulose powder	BP
Maize starch	BP
Sodium lauryl sulphate	BP
Sodium starch glycolate	BP
Methyl Paraben sodium	BP
Propyl Paraben sodium	BP
Poly vinyl pyrrolidone K-30 (P.V.P.K.-30)	BP
Talcum	BP
Magnesium stearate	BP
Cross carmellose sodiumBP	BP
Colloidal silicon dioxide	BP

6.2 Incompatibilities:

None Reported

6.3 Shelf-Life:

36 months from the date of manufacture.

6.4 Special Precautions for Storage:

Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:

10 tablets packed in one blister. Such 10 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

6.6 Special precautions for disposal:

None reported.

7. Registrant:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane,
India.

9. Date of revision of the text: