

GENERIC HEALTHCARE PVT. LTD.

NORFLOZOLE[®]
(Norfloxacin and Metronidazole Tablets)

SUMMARY OF PRODUCT CHARACTERISTICS

1.1 (Invented) name of the medicinal product

NORFLOZOLE[®]

1.2 Strength

Norfloxacin 500 mg & Metronidazole 500 mg (per tablet)

2. Qualitative and quantitative composition

Each film coated tablet contains:

Norfloxacin BP.....400 mg

Metronidazole benzoate BP

equi. to Metronidazole.....500 mg

Colour: Approved colours used

3. Pharmaceutical form

Film-coated tablet.

4. Clinical particulars

4.1 Therapeutic indications

Mixed bacterial infection of aerobes and anaerobes.

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4.2 Posology and method of administration

As directed by the Physician.

4.3 Contraindications

Hypersensitivity to Norfloxacin or any member of quinolone class of anti microbial agents and/or hypersensitivity to Metronidazole or any member of Nitroimidazole group of anti microbial agents.

4.4 Special warnings and precautions for use

Patient should be advised to drink fluids liberally. NORFLOZOLE should be taken at least one hour prior or after food.

4.5 Interaction with other medicinal products and other forms of interaction

Increased levels of plasma Theophylline and Cyclosporine are noticed when these drugs are given concomitantly with Norfloxacin. Multi vitamins, iron and antacid preparations are found to interfere with the absorption of Norfloxacin. Metronidazole has been reported to potentiate the effect of Warfarin and others.

4.6 Pregnancy and lactation

Not established

4.7 Effects on ability to drive and use machines

Not established

4.8 Undesirable effects

Most common side effects with Norfloxacin and Metronidazole are dizziness, nausea, headache, abdominal cramping, anorexia and diarrhoea.

4.9 Overdose

No case of this kind appears to have been reported. In the event of acute overdosage, stomach should be emptied by inducing vomiting or gastric lavage and the patient carefully observed and given symptomatic and supportive treatment. Adequate hydration must be maintained.

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5. Pharmacological properties

5.1 Pharmacodynamic properties

Norfloxacin

Pharmaco-therapeutic group: Norfloxacin is a bactericidal antibiotic belonging to the group of Fluoroquinolones.

ATC Code: J01MA06

Metronidazole

Pharmaco-therapeutic group: Antibacterials for systemic use

ATC code: J01X D01

Norfloxacin inhibits bacterial deoxyribonucleic acid synthesis and is bactericidal. Metronidazole acts as pro-drug in the sense that its metabolites are active and inhibit anaerobic bacterial growth.

5.2 Pharmacokinetic properties

30-40% of Norfloxacin is absorbed from healthy fasting volunteers. Following 200, 400 and 800 mg single dose, 0.8, 1.5 and 2.4 mcg/ml. peak serum concentration is achieved in 3- 4 hours. It is eliminated through bile and renal excretion. About 26-32% of administered dose is recovered in urine and fecal recovery accounts for 30%. Sufficient concentration of drug to inhibit bacterial growth is seen in renal parenchyma, prostate, seminal fluid, testicle, uterus, cervix, vagina, fallopian tube and bile. Administration of Metronidazole in fasting condition produce peak serum concentration in 1.5 hours. Food delays the rate of absorption. Half-life is 8 hours. The major route of elimination of Metronidazole and its metabolites are via urine (60-80% of the dose) with fecal excretion accounting for 6 to 15% of the dose. Metronidazole appears in CSF, saliva and human milk, pus from hepatic abscess in concentration similar to those found in plasma.

5.3 Preclinical safety data

Not established

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline Cellulose, Starch, Magnesium Stearate, Aerosil, Purified Talc, Sodium Starch Glycolate, Croscarmellose Sodium, Instacoat aqua III, Colour Quinoline Yellow

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Lake, Purified water.

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6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C, Protect from light.

6.5 Nature and contents of container

10 tablets are packed in a blister.

Such one blister is packed in a printed carton.

6.6 Special precautions for disposal and other handling

Used samples should be disposed as per local requirement.

7 Registrant

GENERIC HEALTH CARE PRIVATE LIMITED

City Square, 29/A, Office No.205, Shivajinagar,

Pune-411 005, India.

8. Manufacturer

GENERIC HEALTH CARE PRIVATE LIMITED

56, E.P.I.P., Phase No. 1,

Jharmajri, Baddi, HP (India)

9. Date of revision of the text

Not applicable

10. DOSIMETRY (IF APPLICABLE)

Not applicable

11 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

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Not applicable