SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal Product
ROBIFLOX 400, film-coated tablets

2. Qualitative and Quantitative Composition
Each film-coated tablet contains 400mg of Norfloxacin BP

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form
Yellow coloured caplet shape film coated tablets break line on one side and plain on other side

4. Clinical Particulars
4.1 Therapeutic Indications
• Effective in the treatment of gastrointestinal infections, including infectious diarrhea caused by
organisms such as Escherichia coli, Shigella, and Salmonella.
• May be used for bacterial infections of the urinary and gastrointestinal tract when the causative
organisms are sensitive to norfloxacin.
• Used in the management of prostatitis due to susceptible bacterial strains.

4.2 Posology and Method of Administration
Posology

Weight (Age)	Dose per administration	Administration interval	Maximum dail y dose
Adults and children ≥18 years	1 tablet (400 mg)	Every 12 hours	800 mg/day

Usual dose
• 400 mg twice daily (morning and evening).
• Duration of therapy depends on the type and severity of infection (generally 3–10 days).
• Tablets should preferably be taken with a full glass of water and may be taken with or without
food.

Renal impairment
Norfloxacin is eliminated primarily through renal excretion. Dose adjustment may be required in
patients with impaired renal function.
Recommendations:
• Mild impairment — usually no dosage adjustment required.
• Moderate impairment — consider extending the dosing interval.
• Severe renal impairment (creatinine clearance <30 mL/min) — 400 mg once daily may be

recommended.
• Renal function should be monitored during prolonged therapy.
Hepatic impairment
• No specific dose adjustment is usually required in mild to moderate hepatic impairment.
• Use with caution in patients with severe hepatic dysfunction.
• Monitor liver function if treatment is prolonged.
Special clinical situations
• Elderly patients may require monitoring due to reduced renal function.
• Use cautiously in patients with a history of tendon disorders related to quinolone therapy.
• Caution in patients with CNS disorders (e.g., epilepsy) or those receiving drugs that lower the
seizure threshold.
• Avoid unnecessary prolonged therapy to reduce the risk of bacterial resistance.
Stop therapy if:
• Severe hypersensitivity reactions occur.
• Tendon pain, inflammation, or rupture develops.
• Severe diarrhea suggestive of antibiotic-associated colitis occurs.
Method of administration
• Oral route.
• Swallow the tablet whole with a glass of water.
• Maintain adequate hydration during treatment.
• Avoid taking simultaneously with antacids, iron, zinc, or calcium supplements (take at least 2
hours apart).
Frequency of administration
• Usually 400 mg twice daily.
• Dose and duration may be adjusted based on the type of infection and clinical response.
• Use the lowest effective dose for the recommended treatment duration.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Norfloxacin is contraindicated in patients with known hypersensitivity to norfloxacin, other quinolone antibiotics, or any excipients in the formulation. It should not be used in individuals with a history of tendon disorders related to fluoroquinolone therapy. Use is contraindicated
during pregnancy and breastfeeding unless clearly necessary. Norfloxacin is not recommended for children or adolescents under 18 years due to the potential risk of cartilage damage and joint disorders.

4.4 Special Warnings and Special Precautions for Use
Special warnings
Paediatric use
• Not recommended in children and adolescents under 18 years unless clearly indicated, due to potential effects on developing cartilage and joints.

Use with caution in:
• Elderly patients – increased risk of tendon disorders and CNS effects.
• Patients with renal impairment – dose adjustment may be required.
• Patients with seizure disorders or CNS conditions.
• Individuals receiving corticosteroids – increased risk of tendon rupture.
Precautions for Use
• Discontinue therapy if tendon pain, severe hypersensitivity, or persistent diarrhea occurs.
Avoid use in:
• Known hypersensitivity to norfloxacin, other quinolone antibiotics, or any excipients in the
formulation.
• History of tendon disorders (tendinitis or tendon rupture) associated with quinolone therapy.
• Children and adolescents under 18 years, except when clearly indicated.
• Pregnancy and breastfeeding unless the potential benefit outweighs the risk.
• Patients with a history of severe adverse reactions to fluoroquinolone antibiotics.
• Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency due to risk of hemolysis.
Warnings related to excipients
• **Tartrazine (colour):** May cause allergic reactions, including hypersensitivity reactions and bronchial asthma, particularly in individuals sensitive to azo dyes or with aspirin sensitivity.
• **Croscarmellose Sodium and Sodium Starch Glycolate:** Contain sodium; this should be considered in patients on a controlled sodium diet.
• **Microcrystalline Cellulose and Maltodextrin:** Generally regarded as safe, but may cause mild gastrointestinal discomfort in sensitive individuals.
• **Magnesium Stearate and Talc:** Rarely associated with hypersensitivity reactions.
• Residual **Isopropyl Alcohol** and **purified water** are removed during processing and do not pose a safety concern in the finished product.

4.5 Interaction with other medicinal products and other forms of interaction

Central Nervous System Acting Drugs
Alcohol – May increase dizziness, headache, and CNS effects; patients should avoid or limit alcohol during therapy.
Theophylline – Norfloxacin may increase serum theophylline concentrations, leading to toxicity; monitoring is recommended.
Non-steroidal anti-inflammatory drugs (NSAIDs) – Concomitant use may increase the risk of CNS stimulation and seizures.
Important Pharmacological Interactions
1. Warfarin and other anticoagulants – May enhance anticoagulant effect and increase bleeding risk; monitor coagulation parameters.
2. Cyclosporine – May increase cyclosporine levels and nephrotoxicity risk.
3. Probenecid – Reduces renal excretion of norfloxacin, increasing plasma concentrations. Additional Clinically Significant Interactions

4. Antacids containing magnesium or aluminium, and iron, zinc, or calcium supplements – Reduce absorption of norfloxacin; administer at least 2 hours apart.
5. Nitrofurantoin – May antagonize the antibacterial activity of norfloxacin; concurrent use should be avoided.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

Use of Norfloxacin during pregnancy is generally not recommended. Fluoroquinolones may affect
developing cartilage and joints in the fetus. Animal studies have shown potential risks, and
adequate controlled studies in pregnant women are lacking. Therefore, norfloxacin should be used
during pregnancy only if the potential benefit justifies the possible risk to the fetus.

Breastfeeding

Norfloxacin is excreted in small amounts into breast milk. Because of the potential risk of adverse effects on the infant's developing joints, its use during breastfeeding is not recommended. If treatment is necessary, breastfeeding should be discontinued or an alternative antibiotic should be considered.

Fertility

There is no clear evidence that norfloxacin adversely affects human fertility. However, as with
other fluoroquinolones, caution is advised when prescribing to individuals planning pregnancy.

4.7 Effects on ability To Drive and use Machines

Norfloxacin may occasionally cause adverse effects such as dizziness, headache, or light- headedness. These effects could impair the ability to drive or operate machinery in some patients.

Individuals experiencing such symptoms should avoid driving, operating heavy machinery, or performing tasks requiring mental alertness. Caution is advised when norfloxacin is taken with other medicines that may affect the central nervous system. At recommended doses, significant impairment is generally uncommon.

4.8 Undesirable Effects

Gastrointestinal

• Nausea, vomiting, abdominal pain
• Diarrhoea, dyspepsia, loss of appetite
• Rare: antibiotic-associated colitis or severe diarrhoea

Central Nervous System

• Headache, dizziness, fatigue
• Insomnia or restlessness
• Rare: seizures, confusion or hallucinations

Skin and Hypersensitivity

• Rash, itching, urticaria
• Photosensitivity reactions

• Rare: angioedema or severe skin reactions (e.g., Stevens–Johnson syndrome)

Hepatic

• Mild elevation of liver enzymes

• Rare: hepatitis or jaundice

Renal

• Crystalluria or mild renal impairment (rare)

Musculoskeletal

• Tendinitis or tendon rupture, particularly in elderly patients.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via national Pharmacovigilance Electronic Reporting Systems.

4.9 Overdose

Risk Factors

Higher risk may occur in children, elderly patients, and individuals with renal impairment or those taking interacting medicines.

Symptoms

Gastrointestinal: nausea, vomiting, abdominal pain, diarrhoea.

CNS: dizziness, headache, confusion, seizures (rare).

Renal: possible renal impairment.

Other*:* hypersensitivity reactions.

Management

• No specific antidote is available.

• Provide symptomatic and supportive treatment.

• Gastric lavage or activated charcoal may be considered soon after ingestion.

• Maintain hydration and monitor renal function and vital signs until recovery.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Pharmacotherapeutic group: Fluoroquinolone antibacterial

ATC Code: J01MA06

Norfloxacin is a synthetic fluoroquinolone antibiotic with broad antibacterial activity against many Gram-negative and some Gram-positive microorganisms. It acts by inhibiting bacterial DNA gyrase and topoisomerase IV, enzymes essential for DNA replication, transcription, and repair. Inhibition of these enzymes results in disruption of bacterial cell division and leads to bactericidal activity. Norfloxacin is particularly effective against pathogens commonly responsible for urinary tract and gastrointestinal infections.

5.2 Pharmacokinetic Properties

Absorption

Norfloxacin is moderately absorbed from the gastrointestinal tract after oral administration. Peak plasma concentrations are usually reached within 1–2 hours. The absolute bioavailability is approximately 30–40%. Food may delay absorption slightly but does not significantly reduce the
extent of absorption. Adequate plasma levels are achieved for the treatment of urinary and gastrointestinal infections.

Distribution
Norfloxacin is moderately distributed in body tissues and fluids. Plasma protein binding is relatively low (about 10–15%). High concentrations are achieved in urine, kidneys, prostate, and the gastrointestinal tract, which contributes to its effectiveness in urinary and intestinal infections.
Penetration into cerebrospinal fluid is limited.

Metabolism
Norfloxacin undergoes limited hepatic metabolism, producing a small number of metabolites with reduced antibacterial activity. The parent drug remains the major circulating form responsible for therapeutic action.

Elimination
Norfloxacin is eliminated primarily through renal excretion by glomerular filtration and tubular secretion. A significant proportion of the administered dose is excreted unchanged in the urine, resulting in high urinary concentrations. Smaller amounts are eliminated through feces. The
plasma elimination half-life is approximately 3–4 hours. Renal impairment may reduce drug clearance and increase plasma levels; therefore, dose adjustment may be required in patients with significantly reduced renal function.

5.3 Preclinical Safety Data.

Preclinical studies of Norfloxacin have demonstrated relatively low acute toxicity in animal models. Repeated-dose toxicity studies identified effects primarily on the gastrointestinal tract and cartilage
in immature animals, which is consistent with the fluoroquinolone class. Mutagenicity studies were generally negative, and no significant carcinogenic potential was observed in long-term studies.
Reproductive studies showed no major teratogenic effects at therapeutic exposures, although high doses produced embryotoxic effects. Overall, animal data support clinical use at recommended doses with appropriate precautions.

6. Pharmaceutical Particulars

6.1 List of Excipients

Maltodextrine,
Microcrystalline Cellulose,
Cross Povidone,
P.V.P.K-30,
Purified Talc,
Magnesium Stearate,
Sodium Starch Glycolate,
Colloidal Silicone dioxide,
Cross-Carmellose
Sodium,
Ready mix film coating white,
Tartrazine colour supra,
P. Water,
IPA

6.2 Incompatibilities
Not applicable

6.3 Shelf Life
36 Months

6.4 Special Precautions for Storage
Store in air tight container. Protect from light.

6.5 Nature and Contents of Container
10 Tablets are packed in one Blister. 10 Blisters are packed in carton such 10cartons are to be shrink packed and 10 shrinks are to be packed in final shipper.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder
LEXINE TECHNOCHEM PVT.LTD.
Opp Ramakaka Deri,
Chhani, Vadodara- 391 740,
Gujarat, India.

Manufacturer
LEXINE TECHNOCHEM PVT. LTD.
Survey No.373, Opp. Ramakaka Deri, Chhani
Vadodara-391740, Gujarat, India.

8. MARKETING AUTHORISATION NUMBER
10664

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION
April 2026

10. DATE OF REVISION OF THE TEXT
March 2026