SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

ROBIQUINE TABLETS, film coated tablet

2. Qualitative and quantitative composition

Each film coated tablet contains:
250mg of Chloroquine Phosphate BP
16.2mg Lactose
For a full list of excipients, see section 6.1.

3. Pharmaceutical form

White coloured, round shaped, film coated tablets plain on both sides.

4. Clinical particulars

4.1 Therapeutic indications

Chloroquine phosphate tablets are indicated for the treatment and prophylaxis of malaria caused by Plasmodium vivax, P. ovale, P. malariae, and chloroquine-sensitive P. falciparum.

They are also used in the management of extra-intestinal and hepatic amoebiasis, usually in combination with other amoebicidal agents.

Additionally, chloroquine is indicated for chronic inflammatory conditions such as rheumatoid arthritis and systemic or discoid lupus erythematosus due to its immunomodulatory effects.

4.2 Posology & Method of Administration Posology

Weight (Age)	Dose per Administration	Administration interval	**Maximum** daily dose
Adults and children ≥ 15 years (≥50 Kg)	250 mg(1 tablet)	Every 12 hours (or as clinically indicated)	500 mg/day (2 tablets)

Usual dose: 250–500 mg daily depending on indication and national/regional malaria guidelines. Dose adjustment may be required based on disease severity and tolerability.

Renal impairment

Reduced elimination may increase systemic exposure.
Recommended precautions:

- Use the **lowest effective daily dose**
- **Extend dosing interval** (e.g., once daily or every 36–48 hours, depending on tolerance)
- Avoid exceeding **500 mg/day**
- Monitor for gastrointestinal upset, visual symptoms, hypoglycaemia

Hepatic impairment

Chloroquine is hepatically metabolised.

- Initiate therapy at **reduced dosage** (e.g., 250 mg once daily)
- Titrate cautiously based on clinical response and tolerance
- **Do not exceed 250–500 mg/day**
- **Avoid use in severe hepatic dysfunction** unless no safer alternative exists

Special clinical situations

Use the **lowest effective dose** in:

- **Elderly** (greater risk of retinal toxicity & cardiac effects)
- Patients with **pre-existing retinal disease**
- Patients with **renal or hepatic impairment**
- Concomitant **QT-prolonging medication**
- **Glucose-6-phosphate dehydrogenase (G6PD) deficiency** (risk of haemolysis) **Maximum dose should not exceed 10 mg/kg/day (base equivalent)** in any population. **Method of administration**

Oral use.
Tablets should be swallowed whole with a sufficient amount of water. Administration with food or milk reduces gastrointestinal disturbance

Frequency of administration

To maintain therapeutic plasma levels:

- Administer doses **12–24 hours apart**, depending on regimen and indication
- Evening dosing may reduce nausea in sensitive patients

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Chloroquine phosphate tablets are contraindicated in patients with known hypersensitivity to chloroquine or related 4-aminoquinoline compounds. They should

not be used in individuals with pre-existing retinopathy or visual field changes, psoriasis, or porphyria, as the drug may exacerbate these conditions. Use is also contraindicated in patients with severe hepatic impairment and should be avoided in epilepsy unless benefits outweigh risks..

4.4 Special warnings and precautions for use Special warnings

Chloroquine should be used **with extreme caution in children**.
Accidental overdose, especially in young children, may cause **rapidly fatal respiratory depression, cardiovascular collapse, and CNS toxicity**.
This medicinal product **must be kept out of reach of children**

Use with caution in:

- adolescents and adults receiving long-term therapy (risk of cumulative toxicity)
- elderly patients (increased susceptibility to cardiac and ocular effects)

Chloroquine may cause:

- **retinal toxicity**, particularly during prolonged use or at high doses
- **neurological effects** such as headache, confusion, agitation or seizures
- **hypoglycaemia**, which may be severe
  Patients and caregivers should be instructed to recognise warning signs of low blood sugar.

Patients should be advised **not to drive or operate machinery** if visual disturbances, dizziness or altered alertness occur (see section 4.7).

Cardiotoxicity may occur, including:

- conduction disorders
- QT-interval prolongation
- myocardial depression
  Use with caution in patients at risk or taking QT-prolonging medicines.

Precautions for use

Chloroquine should be administered cautiously in patients with:

- **hepatic impairment** (reduced metabolism; avoid high or prolonged doses)
- **renal impairment** (reduced elimination; monitor for toxicity)
- **pre-existing eye disease**, maculopathy or visual field defects
- **G6PD deficiency** (risk of haemolysis)
- **psoriasis or porphyria**, which may be worsened
- **cardiovascular disease or hypertension**

Avoid use in:

- Patients with retinal disease unless benefit clearly outweighs risk.

- Long-term administration without ophthalmic monitoring Regular monitoring is recommended during prolonged therapy:
- Baseline and periodic ophthalmic examinations
- Full blood count and liver function tests
- ECG in patients at cardiac risk

Warnings related to excipients

This medicinal product contains **lactose (16.2 mg per tablet)**.
Patients with rare hereditary problems of **galactose intolerance, total lactase deficiency or glucose- galactose malabsorption** should not take this medicine.

This medicine contains **sodium starch glycolate (8.0 mg per tablet)** and **croscarmellose sodium (5.0 mg per tablet)**.
Although the sodium contribution is minimal, **caution is advised in patients on sodium-restricted diets**.

This product contains **povidone (PVP K30, 5.0 mg per tablet)**.
Hypersensitivity reactions to povidone have been reported, including **rash, pruritus, urticaria and very rarely anaphylaxis**.

This medicine also contains:

- **microcrystalline cellulose (30 mg per tablet)**
- **talc (8.0 mg per tablet)**
- **magnesium stearate (4.5 mg per tablet)**
- **colloidal silicon dioxide (3.5 mg per tablet)**

Although generally well tolerated, patients with **known hypersensitivity** to any of these excipients should avoid use.

4.5 Interaction with other medicinal products and other forms of interaction Central nervous system depressants

 Alcohol – may exacerbate neurological side effects and reduce alertness.
Patients should avoid alcohol during treatment.

 Benzodiazepines – increased risk of sedation and psychomotor slowing.

 Opioid analgesics (e.g., tramadol, morphine, codeine) – risk of additive sedation and respiratory depression.

 Sedating antihistamines (e.g., diphenhydramine, chlorpheniramine) – increased drowsiness and mental clouding.

 Hypnotics and sedatives (e.g., zolpidem) – higher risk of impaired coordination and falls.

 Anxiolytics – combined effect may significantly reduce alertness.

Anticholinergic medicines

Chloroquine may potentiate anticholinergic effects such as **dry mouth, blurred vision, constipation and urinary retention**.

Caution is advised with:

- **Tricyclic antidepressants** (e.g., amitriptyline, imipramine) – increased anticholinergic burden.
- **Antipsychotics** (e.g., chlorpromazine, olanzapine) – higher incidence of anticholinergic and sedative reactions.
- **Antiparkinsonian drugs** (e.g., trihexyphenidyl, benztropine) – intensified effects on vision, bladder function and cognition.
- **Antispasmodics** (e.g., hyoscine, dicyclomine) – additive risk of urinary retention and reduced gastrointestinal motility.

4.6 Fertility, pregnancy and lactation

Pregnancy

Chloroquine phosphate crosses the placenta but, at recommended doses, has been widely used for the treatment and prophylaxis of malaria during pregnancy. Clinical experience indicates no increased risk of congenital malformations when used appropriately. However, prolonged or high-dose therapy should be avoided. Chloroquine should be used during pregnancy only when clearly necessary, and the benefits to the mother outweigh potential risks to the fetus.

Breastfeeding

Chloroquine phosphate is excreted into breast milk in small amounts. At therapeutic doses, the quantity ingested by the infant is minimal and is not considered harmful. Chloroquine may be used during breastfeeding when clinically indicated. However, the amount transferred is insufficient to provide malaria prophylaxis to the infant, so separate protective measures are required. Caution is advised with prolonged or high-dose treatment.

Fertility

There is no evidence from clinical use to suggest that chloroquine phosphate adversely affects human fertility when used at therapeutic doses. Animal studies have not shown significant impairment of fertility.
Chloroquine should be used with caution during long-term therapy, but no specific fertility-related precautions are generally required.

4.7 Effects on ability to drive and use machines

Chloroquine phosphate may cause visual disturbances, dizziness, headache, or blurred vision, which can impair the ability to drive or operate machinery. Patients should be advised not to drive, use machines, or perform tasks requiring visual acuity and alertness if such symptoms occur. Caution is particularly advised at the start of treatment or during dose adjustments.

4.8 Undesirable effects

Adverse reactions to chloroquine are dose-related and more likely with **prolonged use**, **high therapeutic doses**, or **renal/hepatic impairment**.
Severe reactions may occur rapidly following overdose, particularly in children. The frequency categories below follow CIOMS terminology.

Immune System

- **Uncommon:** rash, pruritus, urticaria
- **Rare:** angioedema, photosensitivity
- **Very rare:** anaphylaxis

Nervous System

- **Common:** headache, dizziness
- **Uncommon:** irritability, insomnia
- **Rare:** confusion, agitation, hallucinations, seizures
- **Very rare:** peripheral neuropathy, extrapyramidal symptoms

Eye disorders

- **Uncommon:** blurred vision, accommodation disturbances
- **Rare (with prolonged use):** retinopathy, macular degeneration, visual field defects → Risk increases with cumulative dose
- **Irreversible visual loss** may occur if undetected

Gastrointestinal disorders

- **Common:** nausea, vomiting, abdominal pain, diarrhoea
- **Uncommon:** loss of appetite
- **Rare:** hepatotoxicity, cholestasis

Blood and lymphatic system disorders

- **Rare:** anaemia, leukopenia
- **Very rare:** bone marrow suppression, aplastic anaemia, thrombocytopenia

Skin and subcutaneous tissue disorders

- **Uncommon:** skin rash, pruritus
- **Rare:** hyperpigmentation
- **Very rare:** severe cutaneous adverse reactions including **Stevens–Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)** and **DRESS**
  → Discontinue treatment if rash develops

Hepatobiliary disorders

- **Uncommon:** elevated liver enzymes
- **Rare:** hepatitis, hepatic dysfunction

Reporting of Adverse Drug Reactions:
Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Chloroquine overdose is a medical emergency, especially in children, with rapid onset of toxicity. Symptoms include nausea, vomiting, hypotension, seizures, hypokalaemia, arrhythmias, and sudden cardiac arrest.
Management requires urgent hospital care. Administer activated charcoal if early, provide airway protection, oxygen, and consider intubation. Continuous ECG monitoring, cautious potassium correction, benzodiazepines for seizures, and vasopressors for shock are recommended. No specific antidote; death may occur within hours without prompt treatment.

Symptoms
• Nausea, vomiting, abdominal pain
• Headache, dizziness, blurred or double vision
• Confusion, agitation, seizures
• Hypotension, tachycardia, arrhythmias
• Hypokalemia
• Respiratory distress, cyanosis
• Severe cases: cardiovascular collapse, coma, cardiac arrest

Management
• Urgent hospital admission and continuous monitoring
• Maintain airway, breathing, and circulation
• ECG monitoring and rapid potassium correction
• Early gastric lavage or activated charcoal
• Diazepam for seizures
• Vasopressors to maintain blood pressure
• Mechanical ventilation if required
• Intensive care support until stable

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ANTIMALARIALS, 4-AMINOQUINOLINE DERIVATIVES
ATC code: P01BA01

Chloroquine phosphate is an antimalarial agent belonging to the 4-aminoquinoline class. It acts by inhibiting haem polymerisation within the parasite's food vacuole, leading to accumulation of toxic free haem and parasite death. Chloroquine is effective against erythrocytic forms of susceptible *Plasmodium* species. It also exhibits anti-inflammatory and immunomodulatory effects, which contribute to its usefulness in rheumatoid arthritis and lupus erythematosus.

5.2 Pharmacokinetic properties

Absorption:

Chloroquine phosphate is rapidly and almost completely absorbed from the gastrointestinal tract following oral administration. Peak plasma concentrations are generally reached within 1–3 hours. The drug has high oral bioavailability, and food does not significantly affect its absorption.

Distribution:

Chloroquine is extensively distributed throughout the body and exhibits a large volume of distribution. It accumulates in tissues such as liver, spleen, kidneys, lungs, heart, skin, and eyes, particularly in melanin- containing tissues. Chloroquine is moderately bound to plasma proteins and readily crosses the placenta and blood–brain barrier.

Metabolism:

Chloroquine is primarily metabolized in the liver by cytochrome P450 enzymes to active metabolites, mainly desethylchloroquine and bisdesethylchloroquine. These metabolites contribute to the antimalarial activity of the drug. Hepatic metabolism is slow, which partly accounts for chloroquine's long elimination half-life and potential for accumulation during prolonged therapy.

Elimination:

Chloroquine is eliminated slowly from the body, mainly via renal excretion, with both unchanged drug and metabolites appearing in urine. A smaller proportion is excreted in bile and feces. The drug has a long terminal elimination half-life, ranging from several weeks to months, due to extensive tissue binding and gradual release.

5.3 Preclinical safety data

Preclinical studies indicate that chloroquine phosphate has low acute toxicity at therapeutic doses. In animal studies, high or prolonged dosing produced retinal damage, cardiotoxicity, and hepatotoxicity. Chloroquine showed embryotoxic effects at doses toxic

to the mother, but no clear teratogenic effects were observed. Long- term studies revealed phospholipidosis in multiple tissues. No mutagenic or carcinogenic potential has been demonstrated.

6 Pharmaceutical particulars

6.1 List of excipients

Dicalcium phosphate, Lactose, PVP k30, Talcum, Magnesium stearate, Colloidal silicone dioxide, Sodium starch glycollate, Cross carmillose sodium, MCC 102, Ready mix white film coating, IPA, P water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from moisture, freezing and excessive heat

6.5 Nature and contents of container

10 Tablets are packed in one Blister. 10 Blisters are packed in a carton with insert. Such 100 cartons are packed in one shipper

6.6 Special precautions for disposal and other handling

No special requirements.

7 Marketing Authorization Holder

Lexine
Technochem
PVT. Limited,
Opp Ramakaka
Deri, Chhani,
Vadodara- 391
740, Gujarat,
India.

8 Marketing authorisation number(s)

10663

9 Date of first authorisation/renewal of the authorisation

Date of re-registration: 20/02.2026

10 Date of revision of the text

20/02/2026