# HYDROLOR 200mg TABLET

(Hydroxychloroquine Sulfate)

ہائیڈرولور ۲۰۰ ملی گرام گولیاں

(ہائیڈروکسی کلوروکوئین سلفیٹ)

**DESCRIPTION:**

Hydroxychloroquine is a disease-modifying anti-rheumatic drug (DMARD). It regulates the activity of the immune system, which may be overactive in some conditions. Hydroxychloroquine can modify the underlying disease process, rather than simply treat the symptoms.

The empirical formula is $C_{18}H_{26}ClN_3O_5S$. Molecular Weight 434.0g/mol

**COMPOSITION:**

**Each film coated tablet contains:**

Hydroxychloroquine Sulfate.....200mg

**CLINICAL PHARMACOLOGY:**

**Pharmacokinetics**

Following a single 200 mg oral dose of ***HYDROLOR*** to healthy males, the mean peak blood concentration of hydroxychloroquine was 129.6 ng/mL, reached in 3.26 hours with a half-life of 537 hours (22.4 days). In the same study, the plasma peak concentration was 50.3 ng/mL reached in 3.74 hours with a half-life of 2963 hours (123.5 days). Urine hydroxychloroquine levels were still detectable after 3 months with approximately 10% of the dose excreted as the parent drug. Results following a single dose of a 200 mg tablet versus i.v. infusion (155 mg), demonstrated a half-life of about 40 days and a large volume of distribution. Peak blood concentrations of metabolites were observed at the same time as peak levels of hydroxychloroquine. The mean fraction of the dose absorbed was 0.74. After administration of single 155 mg and 310 mg intravenous doses, peak blood concentrations ranged from 1161 ng/mL to 2436 ng/mL (mean 1918 ng/mL) following the 155 mg infusion and 6 months following the 310 mg infusion. Pharmacokinetic parameters were not significantly different over the therapeutic dose range of 155 mg and 310 mg indicating linear kinetics. The absorption half-life was approximately 3 to 4 hours and the terminal half-life ranged from 40 to 50 days.

Peak plasma levels of Hydroxychloroquine were seen in about 3 to 4 hours. Renal clearance in rheumatoid arthritis (RA) patients taking ***HYDROLOR*** for at least six months seemed to be similar to that of the single dose studies in volunteers, suggesting that no change occurs with chronic dosing.

**Mechanism of Action**

Hydroxychloroquine Sulfate is a 4-aminoquinolin antimalarial an antirheumatic agent. The mechanism underlying the anti inflammatory and imunomodulatory effects of hydroxychloquine in the treatment of Rheumatoid arthritis, chronic discoid lupus erythematosus and systemic lupus erythematosus are not fully known.

**INDICATION AND USAGE:**

Hydroxychloroquine is used to treat: rheumatoid arthritis lupus juvenile idiopathic arthritis . Over the long term Hydroxychloroquine can reduce pain, swelling and joint stiffness. If you have lupus, it may also improve the rash. It may be as long as 12 weeks before you notice the benefits. Hydroxychloroquine is often taken in combination with other drugs such as methotrexate.

**DOSAGE AND ADMINISTRATION:**

Malaria: ***HYDROLOR*** is indicated for the treatment of uncomplicated malaria due to P. falciparum, P. malariae, P. ovale, and P. vivax. ***HYDROLOR*** is indicated for the prophylaxis of malaria in geographic areas where chloroquine resistance is not reported. Limitations of Use in Malaria ***HYDROLOR*** is not recommended for the treatment of complicated malaria. ***HYDROLOR*** is not effective against chloroquine or hydroxychloroquine-resistant strains of Plasmodium species ***HYDROLOR*** is not recommended for the treatment of malaria acquired in geographic areas where chloroquine resistance occurs or when the Plasmodium species has not been identified.

***HYDROLOR*** is not recommended for malaria prophylaxis in geographic areas where chloroquine resistance occurs.

***HYDROLOR*** is indicated for the treatment of chronic discoid lupus erythematosus and systemic lupus erythematosus in adults. Rheumatoid Arthritis ***HYDROLOR*** is indicated for the treatment of acute and chronic rheumatoid arthritis in adults.

**CONTRAINDICATIONS:** Use of ***HYDROLOR*** is contraindicated in patients with known hypersensitivity to 4 aminoquinoline compounds.

**WARNINGS** Resistant strains of malaria: ***HYDROLOR*** is not effective against chloroquine-resistant strains of P. falciparum (see CLINICAL PHARMACOLOGY – Microbiology). ***HYDROLOR*** prolongs the QT interval. Ventricular arrhythmias and torsades de pointes have been reported in patients taking ***HYDROLOR*** (see OVERDOSAGE). Therefore, ***HYDROLOR*** should not be administered with other drugs that have the potential to prolong the QT interval

**DRUG INTERACTIONS:**

**Digoxin:** Concomitant ***HYDROLOR*** and digoxin therapy may result in increased serum digoxin levels: serum digoxin levels should be closely monitored in patients receiving combined therapy.

Insulin or antidiabetic drugs: As ***HYDROLOR*** may enhance the effects of a hypoglycemic treatment, a decrease in doses of insulin or antidiabetic drugs may be required. Drugs that prolong QT interval and other arrhythmogenic drugs: ***HYDROLOR*** prolongs the QT interval and should not be administered with other drugs that have the potential to induce cardiac Reference arrhythmias. Also, there may be an increased risk of inducing ventricular arrhythmias if ***HYDROLOR*** is used concomitantly with other arrhythmogenic drugs.

Mefloquine and other drugs known to lower the convulsive threshold: ***HYDROLOR*** can lower the convulsive threshold. Co-administration of ***HYDROLOR*** with other antimalarials known to lower the convulsion threshold (e.g., mefloquine) may increase the risk of convulsions.

Antiepileptics: The activity of antiepileptic drugs might be impaired if co-administered with ***HYDROLOR***. Methotrexate: Combined use of methotrexate with ***HYDROLOR*** has not been studied and may increase the incidence of adverse effects.
Cyclosporin: An increased plasma cyclosporin level was reported when cyclosporin and ***HYDROLOR*** were co-administered.

**ADVERSE REACTIONS:**

The following adverse reactions have been identified during post-approval use of ***HYDROLOR*** or other 4-aminoquinoline compounds. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Blood and lymphatic system disorders: Bone marrow failure, anemia, aplastic anemia, agranulocytosis, leukopenia, and thrombocytopenia. Hemolysis reported in individuals with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency. Cardiac disorders: Cardiomyopathy which may result in cardiac failure and in some cases a fatal outcome (see WARNINGS and OVERDOSAGE). ***HYDROLOR*** prolongs the QT interval. Ventricular arrhythmias and torsade de pointes have been reported in patients taking ***HYDROLOR*** (see OVERDOSAGE and DRUG INTERACTIONS). Ear and labyrinth disorders: Vertigo, tinnitus, nystagmus, nerve deafness, deafness. Eye disorders: Irreversible retinopathy with retinal pigmentation changes (bull's eye appearance), visual field defects (paracentral scotomas) and visual disturbances (visual acuity), maculopathies (macular degeneration), decreased dark adaptation, color vision abnormalities, Reference ID: 4047416 corneal changes (edema and opacities) including corneal deposition of drug with or without accompanying symptoms (halo around lights, photophobia, blurred vision). Gastrointestinal disorders: Nausea, vomiting, diarrhea, and abdominal pain. General disorders and administration site conditions: Fatigue. Hepatobiliary disorders: Liver function tests abnormal, hepatic failure acute. Immune system disorders: Urticaria, angioedema, bronchospasm Metabolism and nutrition disorders: Decreased appetite, hypoglycemia, porphyria, weight decreased. Musculoskeletal and connective tissue disorders: Sensorimotor disorder, skeletal muscle myopathy or neuromyopathy leading to progressive weakness and atrophy of proximal muscle groups, depression of tendon reflexes and abnormal nerve conduction. Nervous system disorders: Headache, dizziness, seizure, ataxia and extrapyramidal disorders such as dystonia, dyskinesia, and tremor have been reported with this class of drugs. Psychiatric disorders: Affect/emotional lability, nervousness, irritability, nightmares, psychosis, suicidal behavior. Skin and subcutaneous tissue disorders: Rash, pruritus, pigmentation disorders in skin and mucous membranes, hair color changes, alopecia. Dermatitis bullous eruptions including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), photosensitivity, dermatitis exfoliative, acute generalized exanthematous pustulosis (AGEP). AGEP has to be distinguished from psoriasis, although ***HYDROLOR*** may precipitate attacks of psoriasis. It may be associated with pyrexia and hyperleukocytosis.

**STORAGE & INSTRUCTIONS:**

Keep out of reach of children & Store below 30°C.
Protect from sunlight & moisture
Improper storage may deteriorate the medicine
Do not use this medicine after the expiry date which is stated on the blister.

**PRESENTATION:**

***HYDROLOR*** 200mg tablet in pack of 50's.

**ہائیڈرولور** ۲۰۰ملی گرام گولیاں

(ہائیڈروکسی کلوروکوئین سلفیٹ)

خوراک: ڈاکٹر ہدایت کے مطابق استعمال کریں۔

ہدایت: بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں ورنہ دوا خراب ہو جائے گی۔

Manufactured by :

PHARMA LORD

PHARMA LORD (PVT.) LIMITED | 12km, Lahore Road, Layyah. Pakistan

www.pharma-lord.com