HQTOR TABLET

For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

Abbreviated Prescribing information for HQTOR TABLET (Hydroxychloroquine Sulphate 200 mg Tablets) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: Hydroxychloroquine has been found to be useful as an anti-inflammatory and anti-thrombotic agent. It also produces beneficial effects in conditions associated with light sensitivity.

INDICATION: Acute or chronic rheumatoid arthritis in adult patients; Systemic lupus erythematosus (SLE); Polymorphous light eruption (*Under the prescriptions of dermatologist only*).

DOSAGE AND ADMINISTRATION: To be taken with a meal or a glass of milk. Rheumatoid arthritis: Adults 400mg to 600mg daily in divided dose (initial); 200mg to 400mg as a maintenance dose after 4 to 12 weeks of initial dose [Risk of retinopathy if exceeds higher maintenance dose]. SLE: initial 400mg once/twice daily; in case of prolong maintenance therapy 200mg to 400mg should be used. Polymorphous light eruption: 400mg daily in the first month and then 200mg daily for 2-3 months depending on the clinical response. For renal impairments in all indications dose reduction as follows=GFR is 20-50 ml/min, then 75mg daily and if GFR is 10-20 ml/min then 50mg daily.

CONTRAINDICATION: In patients who are hypersensitive to 4-aminoquinoline compounds; retinal or visual field changes attributable to any 4-aminoquinoline compound; long term therapy in children; pre-existing maculopathy of the eye; pregnancy; GFR below 10ml/min.

WARNINGS & PRECAUTIONS: Caution required while long term therapy and irreversible retinal damage; Eye examination in patients dosing exceeds 6.5mg/kg lean body weight, visual acuity below 6/8, renal insufficiency, cumulative dose more than 200g, age more than 65 years; who taking medicine which may cause adverse ocular or skin reactions; patients with severe neurological, gastrointestinal, blood disorders, hepatic disease; psoriasis; porphyria; bone marrow depression; alcoholism; glucose-6-phosphate dehydrogenase deficiency; serious dermatological reactions; metabolic acidosis; cautious while driving and operating heavy machineries. It crosses placenta.

DRUG INTERACTIONS: Interacts with digoxin, aminoglycoside antibiotics, cimetidine, neostigmine, pyridostigmine, intradermal human-diploid cell rabies vaccine, antacids, penicillamine, antidiabetic agents.

ADVERSE REACTIONS: Ocular side effects (blurred/abnormal/color vision, retinopathy, corneal changes); serious dermatological reactions (skin rash, pigmentary changes in soft tissues, bleaching of hair/hair loss, SJS, bullous reactions, erythema multiforme, exfoliative dermatitis, AGEP, precipitate psoriasis, photosensitivity reactions); nausea, vomiting, anorexia, abdominal cramps, vomiting, Irritability, nervousness, emotional changes, nightmares, toxic psychosis, hearing loss, headache, dizziness, vertigo, tinnitus, nystagmus, nerve deafness, convulsions, ataxia, neuromuscular side effects, blood dyscrasias (aplastic anemia, agranulocytosis, leukopenia, thrombocytopenia), bone-marrow depression, hemolysis in G-6-PD deficiency, cardiomyopathy, abnormal liver function tests, fulminant hepatic failure, Allergic reactions (urticaria, angioedema, bronchospasm), weight loss, lassitude, exacerbation or precipitation of porphyria, nonlightsensitive psoriasis, hypoglycemia.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA IN/HQTOR/FEB 2015/01/AbPI (Additional information is available on request)