

HQTOR

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

Abbreviated Prescribing information for **HQTOR** (Hydroxychloroquine Sulphate Tablets I.P.)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

These include interaction with sulphhydryl groups, interference with enzyme activity (including phospholipase, NADH-cytochrome C reductase, cholinesterase, proteases and hydrolases), DNA binding, stabilisation of lysosomal membranes, inhibition of prostaglandin formation, inhibition of polymorphonuclear cell chemotaxis and phagocytosis, possible interference with interleukin 1 production from monocytes and inhibition of neutrophil superoxide release.

INDICATIONS:

The therapeutic indications are as below

200mg

It is indicated for treatment of acute or chronic rheumatoid arthritis in adult patients and for the treatment of systemic lupus erythematosus.

400mg

It is indicated for treatment of acute or chronic rheumatoid arthritis in adult patients and for the treatment of systemic lupus erythematosus.

As an adjunct to diet and exercise to improve glycemc control of patients on metformin, sulfonylurea combination in patients with Type II Diabetes

DOSAGE AND ADMINISTRATION: Dosage: As directed by the Physician.

CONTRAINDICATION: HQTOR is contraindicated in:

– Patients with pre-existing retinopathy of the eye – Patients with known hypersensitivity to 4-aminoquinoline compounds – Children below 6 years of age (200 mg tablets not adapted for weight < 35 kg).

WARNINGS & PRECAUTION: General: Observe caution in patients with gastrointestinal or neurological disorders, in those with sensitivity to quinine, and in porphyria. **Effects on Ability to Drive and Use Machinery:** Patients should be warned. **Carcinogenesis and Mutagenesis:** Reported Non-clinical studies showed a potential risk of chloroquine inducing gene mutations. **Cardiomyopathy:** Cases of cardiomyopathy resulting in cardiac failure. **Electrocardiogram (ECG) Changes and Potential for Cardiac Arrhythmias, Endocrine and Metabolism:** HQTOR has been shown to cause severe hypoglycemia. **Bone marrow depression. Hepatic/Biliary/Pancreatic, Muscular weakness. Extrapyrarnidal reactions, Irreversible retinal damage, Suicidal behaviour, Hepatic Impairment, Renal Impairment.** [Please refer the complete prescribing information for detailed information, available at www.torrentpharma.com]

DRUG INTERACTIONS: HQTOR has the potential to prolong the PR, QRS and/or QTc intervals in a concentration-related manner. Disrupt electrolytes, **Agalsidase:** when HQTOR is co-administered with agalsidase inhibit intra-cellular α -galactosidase activity. Block

neuromuscular junction by aminoglycoside antibiotics. **Antacids** May antacids may reduce absorption of HQTOR. HQTOR may have interaction with **Antiepileptic drugs, Antimalarials, Cimetidine, Cyclosporine, CYP2C8 and CYP3A4 inhibitors, Digoxin, Drugs that prolong the QRS and/or QT interval and other arrhythmogenic drugs, Drugs that affect electrolytes, Insulin, Mefloquine, Neostigmine, Praziquantel, Pyridostigmine, Tamoxifen, Vaccine: Human diploid cell rabies vaccine.** [Please refer the complete prescribing information for detailed information, available at www.torrentpharma.com]

ADVERSE REACTIONS: Ear and labyrinth disorders; Vertigo, tinnitus, **Eye disorders**

; Blurring of vision **gastrointestinal disorders;** abdominal pain, nausea, Diarrhea, vomiting. **Hepatobiliary disorders;** Fulminant hepatic failure **Immune system disorders:** Urticaria, angioedema, bronchospasm, **Metabolism and nutrition disorders;** Anorexia, hypoglycemia. **Musculoskeletal and connective tissue disorders, Nervous system disorders;** Headache, Dizziness. Convulsions. Extrapyrimal reactions such as: akathisia, dystonia, dyskinesia, gait disturbance, tremor. **Psychiatric disorders;** Affect lability. Nervousness. Psychosis, suicidal behavior. **Skin and subcutaneous tissue disorders;** Skin rash, pruritus. Pigmentary changes in skin and mucous membranes, bleaching of hair, alopecia. These usually resolve readily upon cessation of therapy.. Bullous eruptions (including urticarial, morbilliform, lichenoid, maculopapular, purpuric, erythema annulare centrifugum), toxic epidermal necrolysis, erythema multiforme, Stevens-Johnson syndrome, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS syndrome), photosensitivity, exfoliative dermatitis, acute generalized exanthematous pustulosis (AGEP). [Please refer the complete prescribing information for detailed information, available at www.torrentpharma.com]

MARKETED BY:



MARKETED BY TORRENT PHARMACEUTICALS LTD.

IN/HQTOR – 200, 400mg /March -20/01 /AbPI

(Additional information is available on request)