Hydroxychloroquine (Plaquenil)

Hydroxychloroquine belongs to a class of medications known as disease-modifying antirheumatic drugs (DMARDs) and is used to treat certain auto-immune diseases (lupus, rheumatoid arthritis). This drug interferes with lysosomal activity and autophagy, interacts with membrane stability and alters signaling pathways and transcriptional activity, which can result in inhibition of cytokine production and modulation of certain co-stimulatory molecules. It can reduce skin problems in lupus and dermatomyositis and prevent swelling/pain in arthritis.

Resources from Manufacturer

Full Prescribing Information
Sanofi Patient Assistance

Indications and Dosing in Rheumatology

**FDA approved indications*

Adults

- Rheumatoid Arthritis (RA)*
  - Initial dosage: 400 mg to 600 mg daily as a single daily dose or two divided doses. The action of hydroxychloroquine is cumulative and may require weeks to months for maximum therapeutic effect. Daily doses exceeding 5 mg/kg (actual weight) of hydroxychloroquine sulfate increase the incidence of retinopathy.
  - Chronic dosage: 200 mg once daily to 400 mg daily, as a single dose or two divided doses.
- Systemic Lupus Erythematosus (SLE)*: The recommended dosage is 200 mg given once daily, or 400 mg given once daily or in two divided doses.
- Discoid lupus erythematosus (DLE)*: The recommended dosage is 200 mg given once daily, or 400 mg given once daily or in two divided doses.

Other off-label uses:

- Primary Sjogren Syndrome: 200 to 400mg by mouth daily as a single or 2 divided doses; maximum of 5mg/kg/day or 400mg daily whichever is lower
- Dermatomyositis, cutaneous: 300 to 400mg by mouth daily as a single or 2 divided doses; maximum of 5mg/kg/day or 400mg daily whichever is lower
- Sarcoidosis arthropathy, extensive cutaneous disease: 200 to 400mg by mouth daily as a single or 2 divided doses; maximum of 5mg/kg/day or 400mg daily whichever is lower. Therapy may be continued in patients who respond to therapy and then gradually tapered.
- Pediatrics
  - Juvenile dermatomyositis: 5mg/kg/day in 1 to 2 divided doses; maximum daily dose 400mg/day
  - Systemic Lupus Erythematosus: 4 to 6.5mg/kg/day in 1 to 2 divided doses; maximum daily dose 400mg/day

Contraindications

Known hypersensitivity to hydroxychloroquine, 4-aminoquinoline derivatives, or any component of the formulation.

ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

Warnings and Precautions

- Cardiomyopathy and ventricular arrhythmias: Fatal or life-threatening cardiomyopathy and ventricular arrhythmias were reported.
- Retinal toxicity: Irreversible retinal damage is related to cumulative dosage and treatment duration. Baseline retinal exam and exams during treatment are recommended
- Serious skin reactions included Steven Johnson syndrome, toxic epidermal necrolysis have been reported, drug reaction with eosinophilia and systemic symptoms, acute generalized exanthematous pustulosis have been reported.
- Worsening of psoriasis, avoid use in patients with psoriasis unless benefits outweigh risks; may exacerbate or precipitate disease
- Risks Associated with Use in Porphyria: Avoid in patients with porphyria
- Hepatotoxicity was reported in patients with porphyria cutanea tarda
- Hematologic toxicity, discontinue if myelosuppression occurs
- Renal toxicity: Consider phospholipidosis as a possible cause of renal injury in patients with underlying connective tissue disorders. Discontinue hydroxychloroquine if renal toxicity is suspected or demonstrated by tissue biopsy in any organ system.
- Hepatic impairment, use with caution, dose adjustment may be needed
- Renal impairment, use with caution, dose reduction may be needed
- Drug interactions: digoxin, insulin/antidiabetic drugs and drugs that prolong QT interval should be used cautiously with hydroxychloroquine. See full prescribing info for more important drug interactions.

Common Adverse Reactions

Common side effects include: nausea, vomiting, diarrhea and abdominal pain.

Medication Strength and Storage

- Available as 100mg, 200mg, 300mg and 400mg tablets
- Tablets should be stored at room temperature between 59°F to 86°

Medication Administration and Storage

- Administer with food or milk. Do not crush or divide film coated tablets
- CBC and platelet count with differential, liver function, and renal function at baseline and periodically during therapy
- Blood glucose (if symptoms of hypoglycemia occur)
- Muscle strength (especially proximal) and deep tendon reflexes during prolonged therapy;
- Monitor ECG at baseline and as clinically indicated in patients at elevated risk of QTc prolongation.
- Ophthalmologic exam within the first year of prolonged or high-dose treatment to screen for retinal toxicity, followed by annual screening

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