H-Quin™

Hydroxychloroquine Sulfate USP Film Coated Tablet

DESCRIPTION

H-Quin™ is a tablet preparation of Hydroxychloroquine Sulfate. Hydroxychloroquine Sulfate belongs to the 4-aminoquinoline class. Hydroxychloroquine Sulfate has been beneficial for patients with rheumatoid arthritis and lupus erythematosus, especially chronic discoid lupus. The exact mode of action in controlling these diseases is unknown. The action of this compound against malarial parasites is similar to that of chloroquine phosphate.

INDICATIONS

- Rheumatoid arthritis
- Discoid and systemic lupus erythematosus
- Acute attacks of malaria due to *P. vivax, P. malariae, P. ovale,* and susceptible strains of *P. falciparum*

DOSAGE AND ADMINISTRATION

Absolute body weight used as a guide to dosage could result in an overdosage; daily doses should not exceed 6.5 mg (salt form)/kg ideal (lean) body weight.

Rheumatoid Arthritis:

- Initial dosage – In adults, from 400 to 600 mg daily. In a few patients, the side effects may require temporary reduction of the initial dosage. Generally, after five to ten days the dose may be gradually increased to the optimum response level, frequently, without return of side effects.
- Maintenance dosage – When a good response is obtained (usually in four to twelve weeks), the dosage is reduced by 50 percent and continued at an acceptable maintenance level of 200 to 400 mg daily. The incidence of retinopathy has been reported to be higher when the maintenance dose is exceeded.

Lupus Erythematosus:

- Initially, the average adult dose is 400 mg once or twice daily. This may be continued for several weeks or months, depending upon the response of the patient. For prolonged maintenance therapy, a smaller dose, from 200 to 400 mg daily will suffice. The incidence of retinopathy has been reported to be higher when this maintenance dose is exceeded.

Malaria:

Suppression – In adults, 400 mg on exactly the same day of each week. In children (6 years of age and older), the weekly suppressive dose is 5 mg base/kg, but should not exceed the adult dose regardless of body weight. Suppressive therapy should begin two weeks before exposure. When not administered before exposure, give an initial loading dose of 800 mg to adults, or 10 mg base/kg to children in two divided doses, six hours apart. The suppressive therapy should be continued for eight weeks after leaving the endemic area.

Treatment of the acute attack – In adults, an initial loading dose of 800 mg followed by 400 mg in six to eight hours. This is followed by 400 mg on each of the next two days for a total of 2 g of Hydroxychloroquine Sulfate or 1.55 g base. Alternatively, the administration of a single dose of 800 mg has also proved effective. The dosage for adults may also be calculated by body weight.

For children (6 years of age and older) – dosage calculated by body weight is preferred. A total dose representing 25 mg of base/kg is administered over three days as follows:

- **First dose:** 10 mg base/kg (not to exceed 620 mg base)
- **Second dose:** 5 mg base/kg 6 hours after the first dose (not to exceed 310 mg base)
- **Third dose:** 5 mg base/kg 18 hours after the second dose
- **Fourth dose:** 5 mg base/kg 24 hours after the third dose
- For radical cure of vivax and malariae malaria - concomitant therapy with an 8-aminoquinoline compound is necessary.

CONTRAINDICATIONS

• 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 adopted for weight <35 kg)

SIDE EFFECTS

• Abdominal pain, nausea • Diarrhea, vomiting • Anorexia • Headache • Skin rash, pruritus • Affect lability

• Blurring of vision due to a disturbance of accommodation which is dose dependent and reversible

PRECAUTION AND WARNING

Observe caution in patients with gastrointestinal or neurological disorders, in those with sensitivity to quinine, and in porphyria. Patients should be warned about driving and operating machinery since Hydroxychloroquine can impair accommodation and cause blurring of vision. If the condition is not self-limiting, dosage may need to be temporarily reduced.

USE IN PREGNANCY AND LACTATION

Hydroxychloroquine Sulfate crosses the placenta. Data are limited regarding the use of Hydroxychloroquine Sulfate during pregnancy. Hydroxychloroquine Sulfate should be avoided in pregnancy.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Store at or below 25° C temperature. Keep out of reach of children.

PACKAGING

H-Quin™ Film Coated Tablet:

Box containing 2 strips of 10 tablets each. Each film coated tablet contains Hydroxychloroquine Sulfate USP 200 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

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