

ATABRINE hydrochloride,
brand of quinacrine hydrochloride tablets

minutes apart (total dose, 800 mg). Sodium bicarbonate 600 mg with each dose in order to reduce the tendency to nausea and vomiting. **Children from 5 to 10 years, a total dose of 400 mg. Children from 11 to 14 years, a total dose of 600 mg, divided into three or four doses administered ten minutes apart.** Sodium bicarbonate 300 mg with each dose, if desired. (3) Saline purge one to two hours later. The expelled worm is stained yellow, facilitating identification of scolex.

Dwarf Tapeworm-(1) **Adults**, the night before medication 1 tablespoon of sodium sulfate. **Children**, half adult dose. (2) **Adults**, on first day, 900 mg of the antimalarial compound orally, on an empty stomach, in three portions twenty minutes apart, with sodium sulfate purge one and one-half hours later. On the following three days, 100 mg three times daily. **Children from 4 to 8 years**, initial dose of 200 mg, followed by 100 mg after breakfast for three days. **Children from 8 to 10 years**, initial dose of 300 mg, followed by 100 mg twice daily for three days. **Children from 11 to 14 years, initial dose of 400 mg, followed by 100 mg three times daily for three days.**

OVERDOSAGE

Manifestations: Although extremely large doses of quinacrine may prove fatal (eg, 6.8 g intraduodenally, by error in a case of tapeworm infestation), some adults in suicidal attempts have taken enormous doses orally (eg, 7.5, 18, 25 g with unknown amount expelled by vomiting) and have survived. Toxic effects of large doses include excitation of the central nervous system with restlessness, insomnia, psychic stimulation, and convulsions, gastrointestinal disorders (nausea, vomiting, abdominal cramps, diarrhea), vascular collapse with hypotension, shock, cardiac arrhythmias or arrest, and yellow pigmentation of the skin.

Treatment: Treatment is symptomatic with evacuation of the stomach by emesis or gastric lavage. Convulsion & if present, should be controlled before attempting gastric lavage. If due to cerebral stimulation, an ultrastrong-acting barbiturate may be administered cautiously, if due to an-

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oxia, it should be corrected by administration of oxygen, artificial respiration or, in shock, with hypotension, by vasopressor therapy. In vascular collapse, vasopressors should be administered. Because of the importance of supporting respiration, tracheal intubation or tracheostomy may be advisable.

A patient who survives the acute phase and is asymptomatic should be closely observed for at least six hours. Fluids may be forced, and ammonium chloride (8 g daily in divided doses for adults) may be administered to acidify the urine to help promote urinary excretion in cases of both overdosage or sensitivity.

HOW SUPPLIED

Tablets of 100 mg, bottle of 100 (NDC 0024-0082-04)

Winthrop-Breon

Winthrop-Breon Laboratories
Division of Sterling Drug Inc.
New York NY 10016



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ATABRINE®

HYDROCHLORIDE

Brand of
QUINACRINE HYDROCHLORIDE TABLETS
USP

For Chemotherapy of *Giardiasis*,
Tapeworm, and Malaria

WARNING: PHYSICIANS SHOULD COMPLETELY FAMILIARIZE THEMSELVES WITH THE COMPLETE CONTENTS OF THIS LEAFLET BEFORE PRESCRIBING ATABRINE.

DESCRIPTION

Each tablet contains 100 mg of quinacrine hydrochloride, a bright yellow, odorless, bitter crystalline powder that is water soluble (1:35).

Inactive Ingredients: Pharmaceutical Glaze, Starch, Stearic Acid, Talc.

ACTIONS

ATABRINE eradicates certain intestinal cestodes, for example, beef tapeworm (*Taenia saginata*), pork tapeworm (*T. solium*), dwarf tapeworm (*Hymenolepis nana*), and probably fish tapeworm (*Dipyllobothrium latum*), and eliminates *Giardia lamblia* from the intestinal tract. It exerts both suppressive and therapeutic action in malaria. It destroys erythrocytic asexual forms (trophozoites) of vivax, falciparum, and quartan malaria, and sexual forms (gametocytes) of vivax and quartan malaria; however, it is ineffective against falciparum gametocytes and against sporozoites of all forms of malaria.

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INDICATIONS

ATABRINE is indicated for the treatment of giardiasis and cestodiasis. It is also occasionally used for the treatment and suppression of malaria.

CONTRAINDICATIONS

Treatment of pregnant women with cestodiasis or **giardiasis** should be postponed until after delivery because quinacrine crosses the placenta and these conditions generally are not life-threatening.

Since ATABRINE increases the toxicity of the antimalarial agent, primaquine, ATABRINE is contraindicated for concomitant use with this drug.

WARNINGS

Patients should be strongly warned to keep this drug out of the reach of children. Quinacrine occasionally causes a transitory psychosis and therefore should be used with special caution in patients over 60 years of age or in those with a history of psychosis.

In recent years it has been found that certain strains of *Plasmodium falciparum* have become resistant to synthetic antimalarial compounds (including quinacrine) as shown by the fact that normally adequate doses have failed to prevent or cure clinical malaria or parasitemia. Treatment with quinine or other specific forms of therapy is therefore advised for patients infected with a resistant strain of parasites.

Use of ATABRINE in patients with psoriasis may precipitate a severe attack of psoriasis. When used in patients with porphyria the condition may be exacerbated. The drug should not be used in these conditions unless in the judgment of the physician the benefit to the patient outweighs the possible hazard.

Usage in Pregnancy. Usage of this drug in the **suppression** or treatment of malaria during **pregnancy** should be avoided except when in the judgment of the physician the benefit outweighs the possible hazard.

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PRECAUTIONS

Since the drug is known to concentrate in the liver, it should be used with caution in patients with hepatic disease or alcoholism or in conjunction with known hepatotoxic drugs.

Complete blood cell counts should be made periodically if patients are given prolonged therapy. If any severe blood disorder appears which is not attributable to the disease under treatment, discontinuance of the drug should be considered. The drug should be administered with caution to patients having **G-6-PD** (glucose-6-phosphate dehydrogenase) deficiency.

Patients receiving prolonged ATABRINE therapy should be instructed to promptly report any visual disturbances and to receive periodic complete ophthalmologic examinations (see Adverse Reactions).

ADVERSE REACTIONS

The drug temporarily imparts a yellow color to the urine and skin (but does not **cause** jaundice).

Following administration in doses adequate for the treatment of an acute malarial attack, mild and transient headache, dizziness, and gastrointestinal complaints (diarrhea, anorexia, nausea, abdominal cramps and, on rare occasions, vomiting) may occur. Other infrequent but reversible side effects include pleomorphic skin eruptions, neuropsychiatric disturbances (nervousness, vertigo, irritability, emotional change, nightmares, and transient psychosis). Rarely, episodes of convulsions and transient toxic psychosis have been observed after ATABRINE doses of only **50 to 100 mg** three times a **day** for a few days. **Aplastic anemia, hepatitis, and lichen-planus-like eruptions** have been described, especially after long periods of malaria suppressive therapy with quinacrine. **Exfoliative dermatitis** can develop as a primary reaction to the drug or as a **secondary response** to other types of quinacrine-induced symptoms. Contact dermatitis **can** also occur. Epileptiform convulsions have been reported following the administration of massive doses.

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Cases of reversible **corneal** edema or deposits, manifested by visual halos, focusing difficulty and blurred vision, have been reported in patients taking ATABRINE as long-term suppressive therapy for malaria.

Retinopathy has been reported rarely in patients who received relatively high doses of ATABRINE for prolonged periods in **the treatment** of certain chronic diseases. Retinopathy has not been reported as a result of ATABRINE use in malaria suppression **or** in the short-term treatment of parasitic diseases. (See Precautions.)

Single large doses used for the treatment of tapeworm (0.6 g) may produce severe headache, nausea and vomiting, abdominal cramps, and slight diarrhea.

DOSAGE AND ADMINISTRATION

Treatment of **Malaria—Adults** and **children over 8 years**, 200 mg orally with 1 g of sodium bicarbonate every six hours for **5** doses, then 100 mg three times daily for six days (total dosage 2.8 g in seven days). **Children from 4 to 8 years**, 200 mg three times the first day, then 100 mg two times daily for six days. **Children from 1 to 4 years**, 100 mg three times the first day, then 100 mg once daily for six days. Medication should be taken after meals, with a full glass of water, tea, or fruit juice.

Suppression of **Malaria—Adults**, 100 mg orally once daily. **Children**, 50 mg daily. Medication should be maintained for one to three months.

Giardiasis—Adults, 100 mg three times daily for five to seven days. **Children**, 7mg/kg/day given in three divided doses (maximum 300 mg/day) after meals for five days will eradicate the infestation in over 90 percent of children. The stool may be examined two **weeks** later and a repeat course given if indicated. The bitter taste of the pulverized tablets may be disguised by administration **in jam** or honey.

Tapeworm (**Beef, fork, and Fish**)—(1) Preliminary bland, semisolid, nonfat diet, or milk diet on the day before medication, with fasting following the evening meal. A saline purge or **purge** and cleansing enema before treatment if desired. (2) **Adults**, four doses of 200 mg ten

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