PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

QUININE ADCO tablets

COMPOSITION

Each tablet of QUININE ADCO contains 300 mg quinine sulphate.

Excipients:
Magnesium stearate, microcrystalline cellulose, pregelatinised starch, povidone, sodium starch glycolate, talc.

Sugar free

CATEGORY AND CLASS

A 17.1 Peripherally acting muscle relaxants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Quinine is a highly active blood schizonticide and suppresses the asexual cycle of the development of malaria parasites in the erythrocytes. It is effective both as a suppressive medicine and in the overt clinical attack of malaria.

In addition, quinine exerts relaxant effects on skeletal muscle. It increases the tension responses to a single maximal stimulus delivered to the muscle directly or through the nerve but it increases the refractory period of muscle so that the response to tetanic stimulation is reduced. Recumbency leg muscle cramps and congenital myotonia are thus effectively relieved by treatment with quinine.

INDICATIONS

QUININE ADCO is indicated mainly in the treatment of resistant strains of *plasmodium falciparum* malaria.

It is also indicated as a muscle relaxant in congenital myotonia and myotonic contraction as well as nocturnal muscle cramps.

A secondary indication is its use in the diagnostic test for myasthenia gravis.

CONTRAINDICATIONS

- Quinine and its salts, as contained in QUININE ADCO, are contraindicated in patients with a history of hypersensitivity to quinine or any of the excipients and in patients with tinnitus or optic neuritis and especially when this takes the form of cutaneous, angioedematous, visual, or auditory symptoms.
- QUININE ADCO should be discontinued immediately if evidence of haemolysis appears.
- Pregnancy in a patient with malaria is not generally regarded as a contraindication to the use of QUININE ADCO, as malaria infection is potentially serious during pregnancy and poses a threat to the mother and foetus, there appears to be little justification in withholding treatment in the absence of a suitable alternative.
- QUININE ADCO should be avoided in patients with myasthenia gravis, as it may aggravate their condition.

WARNINGS AND SPECIAL PRECAUTIONS

Use of mefloquine with QUININE ADCO may increase the chance of side effects.

Use with mefloquine:
Concurrent use with QUININE ADCO may result in an increased incidence of seizures and of electrocardiogram abnormalities, predisposing the patient to dysrhythmias. It is recommended that mefloquine be administered at least 12 hours after the last dose of QUININE ADCO. Patients taking weekly mefloquine prophylaxis may be found to have mefloquine-resistant malaria that requires treatment with QUININE ADCO, because mefloquine has a very long half-life (approximately 20 days) it will remain in the body long after the medicine has been discontinued. Although there is insufficient information available, if QUININE ADCO must be given to the patient, it is recommended that the patient be hospitalised during administration if possible, and monitored for QT prolongation and possible rhythm disturbances. Seizure activity may also be potentiated in these patients. In patients considered to be at high risk for a seizure, additional precautions and interventions may be indicated.

QUININE ADCO should be used with caution in patients with atrial fibrillation or other serious

heart disease. QUININE ADCO may also cause haemolysis in some types of glucose-6-phosphate dehydrogenase deficiency and should be used with care.

Hypoglycaemia is now recognised to be a frequent complication encountered in falciparum malaria, it is important to recognise that hypoglycaemia may be the cause of coma rather than cerebral malaria and that hypoglycaemia may also be induced by antimalarial therapy.

INTERACTIONS

See WARNINGS AND SPECIAL PRECAUTIONS.

HUMAN REPRODUCTION

Pregnancy in a patient with malaria is not generally regarded as a contraindication to the use of QUININE ADCO, as malaria infection is potentially serious during pregnancy and poses a threat to the mother and foetus, there appears to be little justification in withholding treatment in the absence of a suitable alternative (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Adults:

300 mg to 600 mg given at night for nocturnal cramps.
Treatment is discontinued after several cramp-free nights.

For the treatment of falciparum malaria, a course usually lasts 7 days.

Adults: 600 mg every eight hours for 7 days

Children: 10 mg per kg body-weight every 8 hours for 7 days

In severe or complicated falciparum malaria or when the patient is unable to take oral medication, quinine should be given parenterally, preferably by slow intravenous infusion, but this can be hazardous and patients generally need monitoring for signs of cardiotoxicity.

SIDE EFFECTS

Administration of QUININE ADCO in usual therapeutic doses may give rise to a train of symptoms known as cinchonism, characterised by tinnitus, impaired hearing, headache, nausea and disturbed vision in its mild form. In addition, vomiting, abdominal pain, diarrhoea and vertigo occur in its more severe manifestations. Rashes frequently appear.

Visual disturbances consist of blurred vision, disturbed colour perception, photophobia, diplopia, night blindness, constricted visual fields, scotomata, mydriasis, and very rarely,

even blindness.
Cinchomism may also occur after small doses in patients hypersensitive to QUININE ADCO, but urticuria and flushing of the skin with intense pruritus are the most frequent reactions seen in these patients, other effects include fever, skin rashes and dyspnoea.

Angioedema especially of the face may also occur and asthma can be precipitated.

Thrombocytopenic purpura has been associated with quinine hypersensitivity. Haemoglobinuria occurs rarely.

Other adverse effects of QUININE ADCO may include hypoprothrombinaemia and agranulocytosis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

Main symptoms of overdosage, which can be fatal, include gastrointestinal effects, oculotoxicity, central nervous system disturbances, and cardiotoxicity. Visual disturbances including sudden blindness are usually slowly reversible but there may be residual damage. QUININE ADCO can produce cardiovascular toxicity similar to that seen with quinidine including conduction disturbances, dysrhythmias, anginal symptoms and hypotension leading to cardiac arrest and circulatory failure.

Treatment

In acute overdosage with QUININE ADCO, the stomach should be emptied by lavage if ingestion has been recent. Oral administration of activated charcoal may also be of some benefit. Treatment is mostly symptomatic with attention being given to maintaining blood pressure, respiration and renal function and to treating dysrhythmias.

Central nervous system symptoms are noted in more severe grades of poisoning, particularly noted are: headache, fever, vomiting, apprehension, excitement, confusion, delirium, and syncope. Respiration is first stimulated and is then shallow and depressed. The skin becomes cold and cyanotic as poisoning progresses, the body temperature and the blood pressure fall, weakness is extreme, the pulse is feeble, coma ensues, and death occurs from respiratory arrest.

IDENTIFICATION

Plain, white to off-white, shallow, biconvex tablets.

PROFESSIONAL INFORMATION

PRESENTATION

25 tablets are packed in a white cylindrical polypropylene securitainer with a white polyurethane foam insert and a white low density polyethylene tamper-evident closure.

100 tablets are packed in a white cylindrical polypropylene securitainer with a rayon or white polyurethane foam insert and white low density polyethylene tamper-evident closure.

100 tablets are packed in a white cylindrical high density polyethylene container with white polypropylene cap with heat seal liner, together with rayon and a leaflet.

1 000 tablets are packed in an amber polyvinylchloride container with a white polyurethane foam insert and a white high density polyethylene tamper-evident closure.

Not all pack types and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.
Protect from light and moisture.
Keep in original packaging until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H967 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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