SHREE CEDRINE

PRODUCT NAME:
SHREE CEDRINE (Proguanil Tablets B.P. 100 mg)

DOSAGE FORM:
Tablets

DESCRIPTION OF PRODUCT:
White to almost white colour, circular biconvex uncoated tablets with embossed “CEDRINE” on one side and “P/P” on another side of each tablets.

COMPOSITION (NAME AND STRENGTH OF ACTIVE INGREDIENT):
Each uncoated tablet contains:
Proguanil Hydrochloride BP……..100 mg

INDICATIONS:
Proguanil acts against schizonticides of P. vivax and P. falciparum. It is also effective against pre-erythrocytic forms of P. falciparum. It is used in causal prophylaxis of falciparum malaria.

PHARMACOLOGY:
Proguanil is a biguanide compound which has little antimalarial activity until metabolized in the body to the active antimalarial agent cycloguanil. The usefulness of proguanil is limited by the rapid development of drug resistance by the malarial parasite. Proguanil Hydrochloride is used for the casual prophylaxis of falciparum malaria, to suppress other forms of malaria, and to reduce transmission of infection.

PHARMACOKINETICS:
Proguanil is readily absorbed from the gastrointestinal tract after oral dose, peak plasma concentrations occurring within about 4 hours. Proguanil is metabolised in the liver to the active metabolite Cycloguanil. Peak plasma concentration of cycloguanil occurs approximately 1 hour after those of the parent drug. The elimination half-life of both Proguanil and Cycloguanil are about 20 hours. About 40-60% of Proguanil is eliminated in the urine, of which 60% is unchanged and 30% Cycloguanil. There is also some elimination via faeces. Proguanil is distributed into breast milk in small amount (which are not adequate to provide chemoprophylaxis for the infants.)

DOSAGE & ROUTE OF ADMINISTRATION:
DOSAGE
For oral dose: For prevention of malaria in
Adults and children over 12 years of age: 200 milligrams (mg) (2 tablets) daily, taken after food, beginning at least twenty-four hours before arrival in an area where malaria occurs. Same dose must be taken every day while staying in the area, and every day for four weeks after leaving the area.

Children up to 1 year of age: 25 mg (1/4 tablet) daily, taken after food, beginning at least twenty- four hours before arrival in an area where malaria occurs. Same dose must be taken every day while staying in the area, and every day for four weeks after leaving the area,
Children 1 to 4 years of age: 50 mg (1/2 tablet) daily, taken after food, beginning at least twenty- four hours before arrival in an area where malaria occurs. Same dose must be taken every day while staying in the area, and every day for four weeks after leaving the area.
Children 5 to 8 years of age: 75 to 100 mg (3/4 to 1 tablet) daily, taken after food, beginning at least twenty-four hours before arrival in an area where malaria occurs. Same dose must be taken every day while staying in the area, and every day for four weeks after leaving the area,
Children 9 to 12 years of age: 100 to 150 mg (1 to 1½ tablets) daily, taken after food, beginning at least twenty-four hours before arrival in an area where malaria occurs. Same dose must be taken every day while staying in the area, and every day for four weeks after leaving the area.
Or as directed by the physician.

ROUTE OF ADMINISTRATION:
Oral

CONTRAINDICATIONS:
Hypersensitivity to the active substance or any of the excipients

WARNING & PRECAUTIONS:
Renal Impairment:
Haematological changes in patients with severe renal impairment have been reported. Proguanil tablets should be used with caution in patients with severe renal impairment.

MEDICINES INTERACTIONS:
Antacids
Antacids may reduce the absorption of proguanil, so should be taken at least 2-3 hours apart.
Anticoagulants
Proguanil can potentiate the anticoagulant effect of warfarin and related anticoagulants through a possible interference with their metabolic pathways. Caution is advised when initiating or withdrawing malaria prophylaxis with Proguanil in patients on continuous treatment with anticoagulants.
Boosted protease-inhibitors
When given with boosted protease-inhibitors, reduction in proguanil exposure has been observed. Thiscombination should be avoided when possible.

PREGNANCY & LACTATION:

Pregnancy
There are limited data available from the use of proguanil in pregnant women.
Proguanil should not be used during pregnancy unless, in the judgement of the physician, potentialbenefit outweighs the risk.

Lactation
Although Proguanil is excreted in breast milk, the amount is insufficient to confer any benefit on theinfant. Separate chemoprophylaxis for the infant is required.

SIDE EFFECTS:
Apart from mild gastric intolerance, diarrhoea and some reports of aphthous ulceration there appear to be few adverse effects associated with usual doses of Proguanil hydrochloride. There have been rare reports of hypersensitivity reaction including urticaria and angoedema. Rare cases of seizures and psychotic events have also been reported. Haematological changes have been reported in patients with severe renal impairment.

INCOMPATIBILITIES:
Not applicable

STORAGE:
Store below 25°C. Protect from light and moisture.
Keep all medicine out of reach of children.

STABILITY/ SHELF LIFE:
3 Years from the date of manufacturing.

TYPE AND SIZE OF PACKING:
100'T in HDPE container with individual carton.

SPECIAL PRECAUTION FOR DISPOSAL AND OTHER HANDLING:
No special requirements

SOLE AGENT: SHREE ALOE PHARMACEUTICALS. (NIG) LTD.

NAFDAC REG. NO.: 04-9113

For the use of Registered medical Practitioner or a Hospital or a Laboratory only.

SHREE CEDRINE

(PROGUANIL TABLETS BP 100 mg)

COMPOSITION

Each Uncoated Tablet Contains:
Proguanil Hydrochloride BP.....100 mg

MECHANISM OF ACTION

The active triazine metabolite, inhibits plasmodial dihydrofolate reductase and thus disrupts the synthesis of nucleic acids in the parasite.

INDICATIONS

SHREE CEDRINE is indicated for the Causal prophylaxis of falciparum (P. falciparum) malaria; proguanil also supresses other forms of malaria, and it is used to reduce transmission of infection. Proguanil should not be used alone in countries where chloroquine-resistant malaria has been confirmed

CONTRAINDICATIONS:

Known or suspected hypersensitivity to proguanil

DOSAGE AND ADMINISTRATION

For prophylaxis of malaria:

Adults : Usual dose is 100 mg daily. In highly endemic areas this dose may be safely increased to 200 mg daily. The daily dose is best taken with water after food.
Nonimmune subjects entering a malarious region are advised to begin treatment with proguanil at least 24 hours before arrival. A daily dose of proguanil should be continued for 6 weeks after leaving the area.
Elderly : There are no special dosage recommendations for the elderly, but it may be advisable to monitor elderly patients so that optimum dosage can be individually determined.
Children: Under 1 year: 25 mg daily; 1 to 4 years: 50 mg daily; 5 to 8 years: 75 mg daily; 9 to 12 years: 100 mg daily; over 12 years: adult dose daily.
For a young child, the dose may be administered crushed and mixed with milk, honey or jam.
For all countries with chloroquine-resistant malaria: The dose of proguanil is increased to 200 mg daily with chloroquine (base) given 300 mg once a week, i.e., approximately equivalent to 500 mg chloroquine phosphate.

OVERDOSE:

For more information on the management of overdose or unintentional ingestion, **contact a Poison Control Center** (see Poison Control Center Listing).
Clinical effects of overdose: The following effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)—not necessarily inclusive:
Acute
Epigastric discomfort (abdominal or stomach pain); hematuria (blood in urine; lower back pain; pain or burning while urinating); renal irritation (pain or burning while urinating); or vomiting

Treatment of overdose
Because there is no specific antidote for proguanil overdose, treatment should include the following:
Specific treatment—Symptomatic treatment may be given.
Supportive care—Supportive measures necessary for maintaining the vital functions of the patient may be administered. Patients in whom intentional overdose is confirmed or suspected should be referred for psychiatric consultation.

ADVERSE EFFECTS

At normal therapeutic doses, the adverse effect most commonly encountered is mild gastric intolerance. This usually subsides as treatment is continued. Mouth ulceration has occasionally been reported. Large doses (1 g daily) may cause vomiting, abdominal pain, hematuria and renal irritation. Blood dyscrasias have been reported in patients with renal failure given proguanil.
Selected cases of skin reactions and reversible hair loss have been reported in association with the use of proguanil.

PRECAUTIONS

It is generaly accepted that all drug treatment should be avoided if possible during the first trimester of pregnancy. A causal connection between the use of proguanil and any adverse effect on mother and fetus has never been established, but the attending physician should carefully weigh the expected benefits against the potential risks.

SPECIAL PRECAUTIONS

Renal impairment, Mouth ulcers with renal impairment other medications. Reduced dose necessary in children. The drug passes into breastmilk. Safety in pregnancy not established, although benefits generally considered to outweigh risks. Folate supplements indicated.

DRUG INTERACTIONS

Fluvoxamine : Fluvoxamine can virtually abolish the metabolism of proguanil to its active metabolite cycloguanil via an inhibitory effect on the cytochrome P450 isoenzyme CYP2C19.
Warfarin : For a report of haematuria and high prothrombin ratio in a patient stabilized on warfarin who took proguanil for malaria prophylaxis

STORAGE CONDITIONS

Store in a cool place and protect from light.
Keep all medicines out of reach of children.

PRESENTATION

Jar pack of 100 tablets.

Mfg.Lic.No: KD-493
Nafdac Reg. No: 04-9113

Manufactured By :
Mancare
PHARMACEUTICALS PVT. LTD.
Plot No. 59, 60, 85, 86, V.M.I.E, Dowali Village, Vasai (W), Dist. Thane, Maharashtra, India.
E-mail: mancerp@yahoo.co.in

Sole Agent:
Shree Aloe Pharmaceuticals Co. (Nig) Ltd.
Nigeria.

70 x 39 mm Prepared On : 19Aug2016

SHREE CEDRINE

SHREE CEDRINE

Proguanil
Tablets B.P. 100mg.

100
Tablets

NAFDAC REGN NO. : 04-9113

Mancare

SHREE CEDRINE

Each uncoated tablet contains:
Proguanil Hydrochloride B.P.100mg.

Please read the enclosed leaflet which contains important information.

Keep all medicines away from children.

Store below 30°C

Protected from light

Dosage: As directed by the physician.

SHREE CEDRINE

Proguanil
Tablets B.P. 100mg.

100
Tablets

NAFDAC REGN NO. : 04-9113

Mancare

SHREE CEDRINE

18906062950385

Sole Selling Agent :
Shree Aloe Pharmaceuticals Co., Nig., Ltd
Nigeria

Manufactured By :
Mancare
PHARMACEUTICALS PVT. LTD.
Plot No. 59, 60, 85, 86, V.M.I.E. Dowali Village,
Vasai (W), Dist. Thane, Maharashtra, India.
E-mail: mancerp@yahoo.co.in

42 x 42 x 81 mm

Prepared On : 19Aug2016

Mfg. Lic. No. : KD-493

Batch No. :

Mfg Date :

Exp Date :

Aloe

SHREE CEDRINE

Mancare