PRODUCT INFORMATION

SUMMARY OF PHARMACEUTICAL CHARACTERISTICS

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

DOSAGE FORM:
Tablets

DESCRIPTION OF PRODUCT:
White to almost white colour, circular biconvex uncoated tablets with breakline on one side and "P" embossed on either side of breakline.

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. This combination 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, potential benefit outweighs the risk.

Lactation

Although Proguanil is excreted in breast milk, the amount is insufficient to confer any benefit on the infant. 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.

STORAGE:

Store below 25°C. Protect from light and moisture.
Keep 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.
1000'T in HDPE container.