Prazitel®

1031

Ref. No.:INS031/09.18

Praziquantel

Anthelmintic

PRAZITEL® TABLETS 600MG (FILM COATED)
PRAZITEL® ORAL SUSPENSION 600MG/5ML

PRESENTATION:
Prazitel® Tablets 600mg: White, capsule-shaped film coated tablet embossed 'C' and two breaklines on one side and 'P600' and three breaklines on the other side. Each film coated tablet contains: Praziquantel 600mg.
Prazitel® Oral Suspension 600mg/5mL: Off white, viscous suspension, free from visible evidence of contamination with characteristic odour. Each 5mL contains: Praziquantel 600mg.

CLINICAL PHARMACOLOGY:
Praziquantel is an anthelmintic with a broad spectrum of activity against trematodes (flukes) and cestodes (tapeworms). The drug is rapidly and reversibly taken up by helminths in vitro. At low concentrations it causes increased muscular activity followed by contraction and spastic paralysis. It is this mode of action that causes parasites such as Schistosoma mansoni to loosen its grip on the wall of mesenteric veins and to migrate to the liver. Almost immediately after exposure to it, Praziquantel causes vacuolization and vesiculation of the tegument of the parasite. Through these lesions, host phagocytic cells enter the interior of the parasite eating up its content within a few days. At the molecular level Praziquantel causes the parasite membrane to be more permeable to certain cations such as sodium and calcium.

Pharmacokinetics:
Praziquantel is rapidly absorbed after administration by mouth, even when taken with a meal; more than 80% of a dose is reported to be absorbed. Peak plasma concentrations occur 1 to 4 hours after a dose, but there is a pronounced first-pass effect and Praziquantel undergoes rapid and extensive metabolism in the liver being hydroxylated to metabolites that are thought to be inactive. It is distributed to the CSF. The plasma elimination half-life of Praziquantel is about 1 to 1.5 hours and that of the metabolites about 4 hours. It is excreted in the urine, mainly as metabolites, about 80% of the dose being eliminated within 4 days and more than 90% of this in the first 24 hours. Praziquantel is distributed into breast milk.

USES:
Prazitel® is effective in all forms of schistosomiasis in adults and children. It is used to treat liver flukes infections, lung flukes and intestinal flukes; also tapeworms and neurocysticercosis.

DOSAGE AND ADMINISTRATION:
Prazitel is administered by mouth with food.
In the treatment of schistosomiasis in adults and children over 4 years it is given on one day as three doses of 20 mg/kg at intervals of 4 to 6 hours or it is given as a single dose of 40-60mg/kg. Doses in adults and children in the liver fluke infections clonorchiasis and opisthorchiasis are 25 mg/kg three times daily for one or two days or a single dose of 40 mg/kg. Similar doses may be used in intestinal fluke and lung fluke infections.
Single doses are used in adults and children in tapeworm infections.
Praziquantel is used in the treatment of neurocysticercosis in a dose of 50 mg/kg daily in 3 divided doses for 14 days. A corticosteroid should be given to reduce the severity of adverse effects.

TABLETS

Approximate body weight (kg)	15	18.75	20	22.5	30	37.5	49	52.5	60
Single dose 40mg/kg	1	1 1/4	1 1/3	1 1/2	2	2 1/2	3	3 1/2	4
3 divided doses of 20mg/kg each 4 - 6 hourly	1/2	1/3	2/3	3/4	1	1 1/4	1 1/2	1 3/4	2

NOTE: Side with 3 breaklines gives 4 pieces of 150mg each.
Side with 2 breaklines gives 3 pieces of 200mg each.
Dose to be given after a light breakfast.

Prazitel®

SUSPENSION

Approximate body weight (kg)	15	30	45	60
Dose in mL	5	10	15	20
Single dose 40mg/kg	1 spoonful	2 spoonfuls	3 spoonfuls	4 spoonfuls
3 divided doses of 20mg/kg each 4 - 6 hourly	1/2 spoonful	1 spoonful	1 1/2 spoonfuls	2 spoonfuls

CONTRA-INDICATIONS AND WARNINGS:
Praziquantel should not be used in patients with ocular cysticercosis because of the risk of severe eye damage resulting from destruction of the parasite. Patients should be warned that Praziquantel may cause dizziness or drowsiness and if affected they should not drive or operate machinery during or for 24 hours after treatment.

Adverse Effects:
Adverse effects with Praziquantel may be common but are usually mild and transient . Headache, diarrhoea, dizziness, drowsiness, malaise, abdominal discomfort, nausea and vomiting have been reported most frequently. Hypersensitivity reactions such as fever, urticaria, pruritic skin rashes and eosinophilia can occur. Raised liver enzyme values have been reported rarely. Most patients with neurocysticerosis who are given Praziquantel suffer CNS effects, including headache; hyperthermia, seizures and intracranial hypertension.

Interactions:
Anthelmintic: The plasma concentration of albendazole sulfoxide has been increased by *praziquantel.*
Antiepileptics.: *Carbamazepine* and *phenytoin* have been reported to reduce the bioavailability of praziquantel.
Antimalarials: *Chloroquine* has been reported to reduce the bioavailability of praziquantel.

Pregnancy and Breast-feeding
Praziquantel is distributed into breast milk and mothers should not breast feed during or for 72 hours after treatment.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

®Regd. TM

COSMOS

Cosmos Limited,
Rangwe Rd; Off Lunga Lunga Rd,
Nairobi, Kenya