SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **PZQ Tablet**
1.2 Generic Name : Praziquantel Tablets USP 600mg
1.3 Strength : 600 mg per tablet
1.4 Pharmaceutical Form : Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each film-coated tablet contains:
Praziquantel USP 600 mg
Colour: Titanium Dioxide BP

3. PHARMACEUTICAL FORM

Tablet
White coloured, elongated, biconvex, film coated tablet having three breaklines on both faces of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Praziquantel is indicated for the treatment of species of schistosoma (e.g. Schistosoma mekongi, Schistosoma japonicum, Schistosoma mansoni and Schistosoma hematobium), and infections due to the liver flukes.

4.2 Posology and method of administration

The dosage recommended for the treatment of schistosomiasis is: 3 × 20 mg/kg body weight as a one day treatment. The recommended dose for clonorchiasis and opisthorchiasis is: 3 × 25 mg/kg as a one day treatment. The tablets should be washed down unchewed with some liquid during meals. Keeping the tablets or segments thereof in the mouth can reveal a bitter taste which can promote gagging or vomiting. The interval between the individual doses should not be less than 4 and not more than 6 hours. Praziquantel Tablets is supplied as 600 mg. white film coated oblonged tablet with three scores. The tablet, when broken each of the four segments contain 150 mg. of active ingredient, so that the dosage can be easily adjusted to the patient's body weight. Segments are broken off by pressing the score (notch) with thumbnails. If 1 / 4 of a tablet is required, this is best achieved by breaking the segment from the outer end.

4.3 Contraindications:

Praziquantel should not be given to patients who previously have shown hypersensitivity to the drug. Since parasite destruction within the eye may cause irreparable lesions, ocular cysticercosis should not be treated with this compound.

4.4 Special warnings and special precautions for use:

Patients with or who have a history of cardiac irregularities should be monitored during treatment with praziquantel. Praziquantel has been associated with cardiac arrhythmias, including AV block, bradycardia, ectopic rhythms, and ventricular fibrillation.

4.5 Interaction with other FPPs and Other forms of Interaction

The serum concentration of albendazole may be increased if coadministered with praziquantel. The concomitant use of apalutamide with praziquantel is contraindicated due to the potential for decreased exposure and efficacy of praziquantel. Use of praziquantel with armodafinil, a CYP3A4 inducer, & phenobarbital should be done with caution as concomitant use may produce therapeutically ineffective concentrations of praziquantel.

Hepatic Impairment: Praziquantel should be used with caution in patients with hepatic disease, as reduced hepatic metabolism of praziquantel may result in significantly higher and longer lasting plasma concentrations of unmetabolized praziquantel.

4.6 Pregnancy and lactation

Pregnancy: Praziquantel is excreted in human breast milk. Breast milk concentrations were undetectable 24 to 32 hours after exposure.

Breastfeeding: Consider the benefits of breast-feeding, the risk of potential infant drug exposure, and the risk of an untreated or inadequately treated condition.

4.7 Effects on ability to drive and use machines

Praziquantel may cause dizziness. Patients should be instructed to avoid driving or operating machinery on the day of praziquantel treatment or the day after treatment.

4.8 Undesirable effects

Severe: Ventricular fibrillation, arrhythmia exacerbation, bradycardia, AV blocks, seizures.
Moderate: eosinophilia, elevated hepatic enzymes.
Mild: Urticarial, drowsiness, abdominal pain, vertigo.

4.9 Overdose & Treatment

In an event of overdose of Praziquantel the symptomatic treatment should be provided as per direction of the physician.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Mechanism of action:

Praziquantel is an anthelmintic used in most schistosome and many cestode infestations. Praziquantel affects the permeability of the cell membrane resulting in the contraction of schistosomes. The drug further causes vacuolization and disintegration of the schistosome tegument. The effect is more marked on adult worms compared to young worms. An increased calcium influx may play an important role. Secondary effects are inhibition of glucose uptake, lowering of glycogen levels and stimulation of lactate release. The action of praziquantel is limited very specifically to trematodes and cestodes; nematodes (including filariae) are not affected.

5.2 Pharmacokinetic properties

After oral administration Praziquantel is rapidly absorbed (80%), subjected to a first pass effect, metabolized and eliminated by the kidneys. Maximal serum concentration is achieved in 1-3 hours after dosing. The half-life of Praziquantel in serum is 0.8-1.5 hours.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
1	Starch (Maize)	BP
2	Calcium Carbonate	BP
3	Isopropyl Alcohol	BP
4	Povidone (PVPK-30)	BP
5	Purified Talc (Talcum)	BP
6	Sodium Starch Glycolate	BP
7	Sodium Lauryl Sulphate	BP
8	Magnesium Stearate	BP
Film Coating		
9	Hypromellose (HPMC-15 cps)	BP
10	Colour Titanium Dioxide	BP
11	Macrogol-4000 (PEG-4000)	BP
12	Ethyl Cellulose	IH
13	Diethyl Phthalate	BP
14	Purified Talc (Talcum)	BP
15	Dichloromethane (Methylene Chloride)	BP
16	Isopropyl Alcohol	IH

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from light. Keep container tightly closed. Keep out of reach of children. Keep away from moisture. Store at a temperature not exceeding 30˚C.

6.5 Nature and contents of container

1 blister of 4 tablets packed in a mono pack, such 10 mono packs packed in an outer carton. (4x1x10)

10 blister of 10 tablets packed in a carton (10x10)

100 tablets packed in a white coloured HDPE jar (100’s)

1000 tablets packed in a white coloured HDPE jar (100’s)

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITEADDRESS

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8. MARKETING AUTHORISATION NUMBER

06782/07809/REN/2021:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Jul 13, 2022

10. DATE OF REVISION OF THE TEXT