Summary of Product Characteristics

1. Name of the medicinal product:
Epiquantel Tablet.

2. Qualitative and quantitative composition:
Each tablet contains. ……. 600mg Praziquantel

For excipients see section 6.

3. Pharmaceutical form:
Oblong, film coated tablets divided into four parts.

4. Clinical particulars:
4.1 Therapeutic indications:
Treatment of schistosoma infections due to various types of blood fluke (eg., *Schistosoma haematobium, S.japonicum, S.mekongi, S.mansoni*).

4.2 Posology and method of administration
The doctor must prescribe individual doses for individual cases, according to the diagnosis.
Schistosoma haematobium: 20 mg/kg body weight three times a day at four hourly intervals for one day.
Schistosoma mansoni: 20 mg/kg body weight three times a day at four hourly intervals for one day.
Schistosoma japonicum: 20 mg/kg body weight three times a day at four hourly intervals for one day.
Schistosoma mekongi: 20 mg/kg body weight three times a day at four hourly intervals for one day.
The tablet has 3 score marks, each fragment contains 150 mg active substance, thus allowing a precise dose to be given, corresponding to the patient's body weight.
If 1/4 of a tablet is required, it is convenient to begin by breaking the tablet at one of the outer grooves.
The simplest way to break the tablet is to place the thumbnail in the groove.
Conversion Table:

	BODY WEIGHT IN KG								
	20-25	**26-33**	**34-41**	**42-48**	**49-56**	**57-63**	**64-70**	**71-78**	**79-86**

No. of tablets corresponding to 1 x 20 mg/kg	¾	1	1¼	1½	1¾	2	2¼	2½	2¾

Epiquantel should be swallowed whole with a little liquid, preferably after meals.
Children: see Warnings and Precautions.
Hepatic impairment: see Warnings and Precautions.
Renal impairment: see Warnings and Precautions.

4.3 Contraindications:
Known hypersensitivity to praziquantel or any of the excipients.
Ocular cysticercosis - parasite destruction within the eye may cause irreparable damage.
The concomitant administration of strong inducers of Cytochrome P450 such as rifampicin must be avoided as therapeutically effective plasma levels may not be achieved.

4.4 Special warnings and precautions for use:
Precautions:
Since 80% of praziquantel and its metabolites are excreted in the kidneys, excretion might be delayed in patients with impaired renal function. Nephrotoxic effects of praziquantel are not known.
In uncompensated liver insufficiency and in patients with hepatosplenic schistosomiasis caution should be taken, since due to reduced drug metabolisation in the liver, considerably higher and longer lasting concentrations of unmetabolised praziquantel can occur in vascular and/or collateral circulation leading to prolonged plasma half-life. If necessary, the patient may be hospitalised for the duration of the treatment.
Published in vitro data have shown a potential lack of efficacy of praziquantel against migrating schistosomulae. Data from two observational cohort studies in patients indicate that treatment with praziquantel in the acute phase of infection may not prevent progression into chronic phase.
In addition, the use of praziquantel in patients with schistosomiasis may be associated with clinical deterioration (paradoxical reactions, serum sickness Jarisch-Herxheimer like reactions: sudden inflammatory immune response suspected to be caused by the release of schistosomal antigens). These reactions predominantly occur in patients treated during the acute phase of schistosomiasis. They may lead to potentially life-threatening events e.g., respiratory failure, encephalopathy, and/or cerebral vasculitis. Patients suffering from cardiac irregularities should be monitored during treatment.

When schistosomiasis or fluke infection is found in patients living in or coming from areas with endemic human cysticercosis, it is advised to hospitalise the patient for the duration of treatment.
As praziquantel can exacerbate central nervous system pathology due to schistosomiasis, paragonimiasis or Taenia solium cysticercosis, as a general rule this drug should not be administered to individuals reporting a history of epilepsy and/or other signs of potential central nervous system involvement such as subcutaneous nodules suggestive of cysticercosis.
Neurocysticercosis is not an approved indication due to insufficient data. In animals, venous thrombosis and the development of granulomas at the site of worm attachment has been observed following treatment with praziquantel. Patients treated with praziquantel (for neurocysticercosis) have had a high incidence of severe headache and seizures. Some patients also developed intracranial hypertension. Because of the potential for undiagnosed neurocysticercosis to be present in patients originating from endemic areas, extra care is necessary in managing such patients. If cerebral cysticercosis is present and treatment is still considered essential, the patient should be hospitalised under specialist care.

4.5 Interaction with other medicinal products:
Praziquantel is believed to be metabolised via the CYP450 enzyme system. Many categories of drugs are known to inhibit or induce CYP450 enzymes causing an increase or decrease in serum concentrations or bioavailability. Care must therefore be exercised when co-administering such drugs.
Concomitant administration of drugs that increase the activity of drug metabolising liver enzymes (CYP450 inducers), e.g., antiepileptic drugs, dexamethasone may reduce plasma levels of praziquantel. Concomitant administration of strong inducers of CYP450 such as rifampicin must be avoided. Chloroquine, when taken simultaneously, can lead to lower concentrations of praziquantel in blood.
Concomitant administration of drugs that decrease the activity of drug metabolising liver enzymes (CYP450 inhibitors) e.g. cimetidine, ketoconazole, itraconazole, erythromycin, may increase plasma levels of praziquantel.
Co-administration of grapefruit juice and praziquantel is not recommended. Co-administration has been reported to increase praziquantel C_{max} by 1.6 (90% Cl 1.05, 2.0) and AUC by 1.9 (90% Cl 1.03, 2.47). The effect of this increase in exposure on efficacy and safety of praziquantel has not been studied.

4.6 pregnancy and lactation:
Use in Pregnancy (Category B1)
There are no adequate and well controlled studies on the use of praziquantel in pregnant women.
Because animal reproduction studies are not always predictive of human response, for safety reasons **Epiquantel** should not be used in pregnancy unless clearly needed.
Use in Lactation

Praziquantel has been reported to be excreted in the milk of nursing women. Women should not nurse on the day of **Epiquantel** treatment and during the subsequent 72 hours.

4.7 Effects on ability to drive and use machines:
Patients should be warned not to drive a car and not to operate machinery on the day of EPIQUANTEL treatment and the following day.

4.8 Undesirable effects:
Side effects vary according to dose and duration of praziquantel medication; furthermore they are dependent on the parasite species, extent of parasitisation, duration of infection and localisation of the parasites in the body. Side effects occur earlier and are more frequent and pronounced in patients with severe parasitic infestation. Mild increases in liver enzymes have been reported in some patients. Frequencies of Adverse Reactions are mainly based on data from medical literature.

Immune system disorders:
Very Rare: Allergic reaction, polyserositis, eosinophilia.
Nervous system disorders:
Very Common: Headache, Dizziness.
Common: Vertigo, Somnolence
Very Rare: Seizures.
Cardiac disorders:
Very Rare: Unspecified arrhythmias.
Gastrointestinal disorders:
Very Common: Gastrointestinal and abdominal pains, nausea, vomiting.
Common: Anorexia, diarrhea (very rarely bloody diarrhea).
Skin and Subcutaneous tissue disorders:
Very Common: Urticaria.
Common: Rash.
Very Rare: Pruritus.
Musculoskeletal and Connective tissue disorders:
Common: Myalgia.
General disorders and Administration site conditions:
Very Common: Fatigue.
Common: Feeling unwell (asthenia, malaise), fever.
It is often not clear whether the complaints reported by patients or the undesirable effects reported by the physician are caused by praziquantel itself (I, direct relation), or may be considered to be an endogenous reaction to the death of the parasites produced by praziquantel (II, indirect relation), or are symptomatic observations of

the infestation (III, no relation). It may be difficult to differentiate between the possible variations I, II and III.

4.9 Overdose:
Information on overdosage in humans is not available. Treatment should be supportive and provide symptomatic care.
Activated charcoal may reduce absorption of the drug if given within one to two hours after ingestion. In patients who are not fully conscious or have impaired gag reflex, consideration should be given to administering activated charcoal via a nasogastric tube, once the airway is protected.

5. Pharmacological properties:
5.1 Pharmacodynamic properties:
Animal studies show that praziquantel induces a rapid contraction of schistosomes by a specific effect on the permeability of the cell membrane. The drug further causes vacuolisation and disintegration of the schistosome tegument. The effect is more marked on the adult than on young worms.

5.2 Pharmacokinetic properties:
After oral administration praziquantel is rapidly absorbed (80%). It is, however, subject to first pass effect and extensive metabolism. One hour after administration approximately 6% only of the drug in serum is in the unmetabolised form. Both the unchanged drug and the metabolites are excreted primarily by the kidneys.
Maximal serum concentration is achieved 1-3 hours after dosing. The half life of praziquantel in serum is 0.8-1.5 hours.

5.3 Preclinical safety data
Not stated.

6. Pharmaceutical particulars:
6.1 List of excipients:
Maize starch, povidone K 30, microcrystalline cellulose 101, sodium lauryl sulfate, magnesium stearate, polyplasdone XL, hydroxypropyl methyl cellulose 2910, polyethylene glycol 6000, polyethylene glycol 35000, titanium dioxide, purified talc.

6.2 Incompatibilities:
None known

6.3 Shelf life:
3 years

6.4 Special precautions for storage:

Storeat a temperature not exceeding 30°C.

6.5 Nature and contents of container:
A carton box containing 4or 100 or 1000 tablets. Each 4 tablets are blistered in printed Aluminum Foil/PVC blister and an inner leaflet.

6.6 Special precautions for disposal and other handling:
Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. Marketing authorisation holder:
EIPICO

8. MARKETING AUTHORISATION NUMBER(S)

06214/07564/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
24-07-2026

10. Date of revision of the text
July 2017