

1.4 Product Information

1.4.3 Patient information leaflet

Praziquantel Tablets USP 600mg

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your health care provider. This includes any **possible** side effects not listed in this leaflet. See section 4.

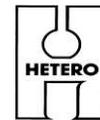
What is in this leaflet

1. What Praziquantel Tablets 600mg is and what it is used for
2. What you need to know before you take Praziquantel Tablets 600mg
3. How to take Praziquantel Tablets 600mg
4. Possible side effects
5. How to store Praziquantel Tablets 600mg
6. Contents of the pack and other information

1. WHAT PRAZIQUANTEL TABLETS 600MG IS AND WHAT IT IS USED FOR

Praziquantel Tablets 600mg is one of a group of medicines called “antihelmintics”. The active substance is praziquantel. Praziquantel Tablets 600mg acts against various types of blood fluke worms (schistosomes) which cause schistosoma infections.

Praziquantel Tablets 600mg is used in adults and children over 6 years for mass drug administration in communities affected by schistosomiasis. You are being given these tablets under a mass drug administration programme in which Praziquantel Tablets 600mg is



administered depending on the risk of transmission. Mass drug administration works to interfere with the transmission of the disease by destroying the parasites.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRAZIQUANTEL TABLETS 600MG

Do not take Praziquantel Tablets 600mg if you

- Are allergic (hypersensitive) to praziquantel or to any of the other ingredients of Praziquantel Tablets 600mg.
- have cysticercosis of the eye. Parasite destruction within the eye may cause serious ocular damage

are taking rifampicin (an antibiotic for treating tuberculosis). Rifampicin decreases the level of Praziquantel Tablets 600mg in the body. Therapeutically effective plasma levels of Praziquantel Tablets 600mg may not be achieved.

Take special care with Praziquantel Tablets 600mg

Tell your health care provider if you

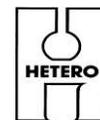
- have liver problems
- suffer from heart disease, including heart rhythm problems
- have a history of epilepsy or suffer from convulsions (fits)
- have worm infections of the brain.

Taking other medicines: Tell your health care provider immediately if you are taking rifampicin (an antibiotic for treating tuberculosis) as these should not be taken with Praziquantel tablets 600mg (see section: “Do not take Praziquantel Tablets 600mg if you”). Concomitant use of carbamazepine, phenytoin, phenobarbital (used for treating fits) and dexamethasone (steroid medication) is not recommended.

There are some medicines that may interact with Praziquantel Tablets 600mg. Make sure your health care provider knows if you are taking any of the following medicines:

- Cimetidine (used to prevent and treat ulcers of the stomach and intestines)
- Ketoconazole, itraconazole (used to treat fungal infections)
- Erythromycin (used to treat infections)
- Chloroquine (used to prevent and treat malaria)

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.



Taking Praziquantel Tablets 600mg with food and drink

You should preferably take your medicine during or after a meal.

Don't drink grapefruit juice on the day you take Praziquantel Tablets 600mg.

Pregnancy and breast-feeding

Tell your health care provider if you are pregnant, trying to become pregnant or breast-feeding.

You should not breast-feed on the day of treatment with Praziquantel Tablets 600mg and during the subsequent 24 hours.

Ask your health care provider for advice before taking any medicines.

Driving and using machines

When driving vehicles or using machines on the day of treatment, it should be taken into account that occasionally dizziness, somnolence or fits may occur.

3. HOW TO TAKE PRAZIQUANTEL TABLETS 600MG

Praziquantel Tablets 600mg will be given to you by a health care provider as part of the mass drug administration programme.

- Always take your medicine exactly as your health care provider has told you. Tablets should be swallowed in the presence of the health care provider.
- You should check with your health care provider if you are unsure of the instructions.
- Praziquantel Tablets 600mg should be swallowed whole with some liquid, preferably during or after meals.

How much will be given

Your health care provider will decide how much to give to you. Treatment is given to you as a single dose.

Height (cm/inches)	Number of tablets (mg) of Praziquantel Tablets USP 600mg
94-109 cm (37-42 inches)	1 tablet (600 mg)
110-124 cm (43-48 inches)	1 ½ tablets (900 mg)
125-137 cm (49-53 inches)	2 tablets (1200 mg)
138-149 cm (54-58 inches)	2 ½ tablets (1500 mg)
150-159 cm (59-62 inches)	3 tablets (1800 mg)



160-177 cm (63-69 inches)	4 tablets (2400 mg)
≥178 cm (>70 inches)	5 tablets (3000 mg)

Intervention frequency is determined by the prevalence of infection in school-aged children or visible haematuria. In high-transmission areas, treatment is given to you once per year and may have to be repeated every year for a number of years.

Use in children <4 years

There is no documented information on the safety of praziquantel for children under 4 years of age (or under 94 cm height). These children should therefore be excluded from mass preventive treatment but can be treated on an individual case by case basis.

Elderly

The usual adult dose should be given.

Patients with liver problems

Your health care provider may change your dose, depending on your liver function.

If you take more Praziquantel Tablets 600mg than you should

Taking too many tablets at once may make you unwell. Contact your health care provider or your nearest hospital casualty department at once. Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

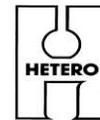
4. POSSIBLE SIDE EFFECTS

Like all medicines, Praziquantel Tablets 600mg can cause side effects, although not everybody gets them.

A few people develop allergic reactions although serious allergic reactions are very rare. If you get any of the following symptoms, tell your health care provider immediately.

- sudden wheezing, difficulty in breathing or tightness in the chest
- swelling of eyelids, face or lips
- itching all over the body reddening of the skin or itchy red spots
- Skin rash
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).

Other side effects:



Additionally, if any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Very common side effects which affect 1 to 10 users in 10 are listed below:

- Headache
- Dizziness
- Stomach discomfort, abdominal pains, feeling sick, vomiting
- urticaria
- fatigue (feeling tired)

Common side effects which affect 1 to 10 users in 100 are listed below:

- Vertigo (spinning sensation and loss of balance)
- Somnolence (sleepiness or drowsiness)
- Anorexia (loss of appetite)
- Diarrhoea (losing weight)
- Myalgia (muscle pain)
- Malaise (feeling unwell)
- Fever

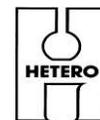
Rare side effects which affect 1 to 10 users in 10,000 are listed below:

- Liver function tests increased

Very rare side effects which affect 1 to 10 in 100,000 are listed below:

- Allergic reactions
- increased eosinophils
- Polyserositis (inflammation of serous membranes)
- fits (seizures)
- Heart rhythm problems
- Bloody diarrhoea

Side effects may be more frequent and/or serious in patients with a heavy worm burden. It is often not clear whether the complaints reported by patients or the undesirable effects reported by the health care provider are caused by praziquantel itself, or may be considered to be an endogenous reaction to the death of the parasites produced by praziquantel, or are symptomatic observations of the infestation.



5. HOW TO STORE PRAZIQUANTEL TABLETS 600MG

Keep out of the sight and reach of children.

Store below 30°C.

Keep blisters in the provided outer carton to protect from light.

Do not use Praziquantel tablets 600mg after the expiry date, which is stated on the pack after EXP. The expiry date refers to the last day of the month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Praziquantel Tablets 600mg contains

The active substance is praziquantel.

The other ingredients are: Pre gelatinized starch, Povidone, Sodium lauryl sulphate, Purified water, Magnesium stearate, Microcrystalline cellulose, Opadry white 03F580079

Film coating Opadry white 03F580079 ingredients are: Hypromellose, Titanium dioxide, Macrogol

What Praziquantel Tablets 600mg looks like and content of the pack

Praziquantel Tablets 600mg are white to orange tinged, oblonged, film coated tablets with three scores on one side and two scores on the other side. The tablet is de-bosed with “P8” on one side and “H” on the other side.

The tablets are packed in

Container pack:

6's Count: 40cc H.W HDPE container with 33mm CR closure with purified cotton.

100's Count: 200cc H.W HDPE container with 38mm CR closure with purified cotton.

500's Count: 750cc H.W HDPE container with 53mm CT closure with purified cotton.

1000's Count: 1500cc H.W HDPE container with 53mm CT closure with purified cotton.

Blister pack:

1 x 6's and 10 x 10's Alu-Alu Blister pack: Cold Form foil (60µ PVC/45µ aluminium/25 OPA) - 25µ plain aluminium foil.

Supplier and Manufacturer:

Supplier	Manufacturer
Hetero Labs Limited 7-2-A2, Hetero Corporate	Hetero Labs Limited, Unit - V Survey No. 439, 440, 441 & 458,



Module 1-Administrative Information And Product Information

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