



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
PRAZIQUANTEL 600MG TABLETS
Praziquantel

Read this leaflet carefully before you 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.

What is in this leaflet?

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

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

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

Praziquantel 600mg Tablets is used in adults and children (6 yrs above) for mass drug administration in communities affected by schistosomiasis. You are being given these tablets under a mass drug administration programme in which Praziquantel 600mg Tablets 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 600MG TABLETS

Do not take Praziquantel 600mg Tablets if you

- are allergic to praziquantel or to any of the other ingredients of this medicine.
- have cysticercosis of the eye. Parasite destruction within the eye may cause serious ocular damage.
- are taking rifampicin (an antibiotic for treating tuberculosis). Therapeutically effective plasma levels of Praziquantel 600mg Tablets may not be achieved.

Warnings and precautions

Talk to your health care provider before taking Praziquantel 600mg Tablets 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 and Praziquantel 600mg Tablets

Tell your health care provider if you are taking, have recently taken or might take any 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 600mg Tablets (see section: “Do not take Praziquantel 600mg Tablets 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 600mg Tablets. Make sure your health care provider knows if you are taking any of the following medicines:

- cimetidine (inhibits stomach acid production)
- ketoconazole, itraconazole (used for treating fungal infections)
- erythromycin (used to treat infections)
- chloroquine (used to 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.



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Praziquantel 600mg Tablets with food and drink

You should preferably take your medicine during a meal. Don't crush tablets. Don't drink grapefruit juice on the day you take Praziquantel 600mg Tablets.

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 600mg Tablets 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 600MG TABLETS

Praziquantel 600mg Tablets 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 provide has told you. Check with your health check provider if you are not sure.
- 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 600mg Tablets should be preferably taken during 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 600mg Tablets
Centimeters (cm)	Inches	Feet (ft)	
94-109 cm	37-42 inches	3.10-3.56 ft	1 tablet (600 mg)
110-124 cm	43-48 inches	3.60-4.06 ft	1 ½ tablets (900 mg)
125-137 cm	49-53 inches	4.10-4.49 ft	2 tablets (1200 mg)
138-149 cm	54-58 inches	4.52-4.88 ft	2 ½ tablets (1500 mg)
150-159 cm	59-62 inches	4.42-5.21 ft	3 tablets (1800 mg)
160-177 cm	63-69 inches	5.24-5.80 ft	4 tablets (2400 mg)
≥178 cm	≥70 inches	≥4.83 ft	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 doctor may change your dose, depending on your liver function.

If you take more Praziquantel 600mg Tablets 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.



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4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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 (may affect more than 1 in 10 people) are listed below:

- headache
- dizziness
- stomach discomfort, abdominal pains, feeling sick, vomiting
- urticaria
- feeling tired

Common side effects (may affect up to 1 in 10 people) are listed below:

- vertigo
- somnolence
- anorexia
- diarrhoea (losing weight)
- muscle pain
- feeling unwell
- fever

Rare side effects (may affect up to 1 in 1,000 people) are listed below:

- liver function tests increased

Very rare side effects (may affect up to 1 in 10,000 people) 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 600MG TABLETS

- Keep this medicine out of the sight and reach of children.
Store below 30°C.
- Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of the month.
- Do not throw away any medicines via wastewater. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

1. CONTENTS OF THE PACK AND OTHER INFORMATION



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What Praziquantel 600mg Tablets contains



Each tablet contains 600mg of praziquantel.

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

Praziquantel 600mg Tablets is 1x10 tablets in a sachet.

Supplier and Manufacturer

Fidson Healthcare Plc
Km 38, Lagos Abeokuta Expressway,
Sango Ota
Ogun State

Approval of PIL text	Prepared by	Approved by:	Approved by:
Signature			
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