

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[NT011 trade name][†]
Praziquantel

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly .*

Read all of 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 questions about the medicine, 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 seem to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [NT011 trade name] is and what it is used for
2. What you need to know before you take [NT011 trade name]
3. How to take [NT011 trade name]
4. Possible side effects
5. How to store [NT011 trade name]
6. Contents of the pack and other information

1. What [NT011 trade name] is and what it is used for

[NT011 trade name] is one of a group of medications called “anthelmintics” and contains the active substance praziquantel. [NT011 trade name] acts against various types of blood fluke worms (schistosomes) which cause schistosoma infections.

[NT011 trade name] is used in adults and children for mass drug administration in communities affected by schistosomiasis. You are being given these tablets under a program to reduce the transmission of schistosomiasis by killing the parasites that cause the disease.

2. What you need to know before you take [NT011 trade name]

Do not take [NT011 trade name] if you

- are allergic to praziquantel or any of the other ingredients of this medicine (listed in Section 6).
- have cysticercosis of the eye. Parasite destruction within the eye may cause serious damage to your eye that could lead to blindness.
- are taking rifampicin (used to treat tuberculosis). Rifampicin will reduce the blood levels of [NT011 trade name] making it less effective.

Warnings and precautions

Tell your healthcare provider before taking [NT011 trade name] if you:

- have liver problems,
- suffer from heart disease, including problems with your heart rhythm,
- have a history of epilepsy or suffer from convulsions (fits),

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency’s responsibility.

- Have a history of cysticercosis nodules (bumps) just under the skin,
- have a worm infection of the brain.

Taking other medicines and [NT011 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines and natural health products obtained without a prescription.

Taking carbamazepine, phenytoin and phenobarbital (used for treating fits) or dexamethasone (steroid medication) with [NT011 trade name] is not recommended.

There are other medicines that may interact with [NT011 trade name]. Make sure your health care provider knows if you are taking any of the following medicines:

- cimetidine (to reduce stomach acid)
- ketoconazole or itraconazole (used to treat fungal infections)
- erythromycin (an antibiotic)
- chloroquine (used to treat malaria)

[NT011 trade name] with food and drink

You should take your medicine during a meal. Do not crush or chew the tablets. The bitter taste of the tablets is very unpleasant. Don't drink grapefruit juice on the day you take [NT011 trade name].

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 [NT011 trade name] and for the next 3 days.

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

Driving and using machinery

[NT011 trade name] may cause dizziness, drowsiness and fits. Do not drive or operate machinery on the day of treatment and the following day.

3. How to take [NT011 trade name]

[NT011 trade name] will be given to you or your child by a healthcare provider as part of a mass drug administration programme.

Always take your medicine exactly as your health care provider has told you. Check with your health check provider if you are not sure.

[NT011 trade name] should be taken with a meal.

How many tablets will you be given?

The number of tablets to take depends on your height as described in the table below.

Height (cm/inches)	Number of [NT011 trade name] tablets (mg)
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)

You may need to repeat the treatment depending on how common schistosoma infections are in your area. For example, in high-transmission areas, treatment is given once per year and may need to be repeated every year for several years. Where schistosoma infections are less widespread, treatment may only need to be given every other year or be given just to children during their school years.

Children aged less than 4 years

There is not enough information on the safety of praziquantel for children under 4 years of age (or under 94 cm in height). These children are excluded from the mass drug administration program but can be treated if needed on a case-by-case basis.

Elderly

The usual adult dose should be given.

Patients with liver problems

If you have liver disease, your healthcare provider may change the dose to be taken.

If you take more [NT011 trade name] than you should

You will normally be given the right amount of medicine by a health care provider so the chances of taking too many tablets should be small. Taking too many tablets at once may make you feel unwell. Contact your health care provider or your nearest hospital emergency department if you take more than the recommended number of tablets.

4. Possible side effects

Like all medicines, [NT011 trade name] can cause side effects, although not everybody gets them.

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

- Sudden wheezing, difficulty with breathing or tightness in the chest
- Swelling of the eyelids, face, or lips
- Itching all over the body
- Reddening of the skin, itchy spots, or other skin rash
- Severe skin reactions such as a rash that causes blistering and may affect the mouth and tongue.

Other side effects

If any of the following side effects are severe, or if you notice any side effects not listed below, please tell your health care provider.

Very common side effects (may affect more than 1 in 10 people):

- Headache
- Dizziness
- Abdominal pain, nausea, or vomiting
- Feeling tired
- Itchy rash

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

- Vertigo (sensation of the world spinning around you)
- Sleepiness
- Loss of appetite
- Diarrhoea
- Muscle pains
- Feeling generally unwell
- Fever

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

- Liver function tests increased

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

- Allergic reactions
- Increased eosinophils (a type of white blood cell)
- Polyserositis (inflammation of the membranes that surround joints)

- Fits (seizures or convulsions)
- Changes to the rhythm of your heart
- Bloody diarrhoea

Side effects may be more frequent and/or serious in patients who are heavily infected with worms. It is often not clear whether the side effects are caused by the medicine itself, a reaction to the death of parasites caused by the medicine, or symptoms caused by the worm infection.

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

5. How to store [NT011 trade name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton, blister and bottle label after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [NT011 trade name] contains

- The active ingredient is praziquantel.
- The other ingredients of [NT011 trade name] are:
Core tablet: Pregelatinized starch, Povidone, Sodium lauryl sulfate, Microcrystalline cellulose, Magnesium stearate

Film coat: Hydroxypropyl methylcellulose, Titanium dioxide, Macrogol/ PEG, Sodium lauryl sulfate

What [NT011 trade name] looks like and contents of the pack

White to orange tinged, oblong, film-coated tablet with three scores on one side and two scores on the other side. The tablet is debossed with "P8" on one side and "H" on the other side.

The tablet can be divided into either two or four equal doses.

Supplier and Manufacturer

Supplier

Hetero Labs Limited
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Manufacturer

Hetero Labs Limited, Unit-V
Survey No. 439, 440, 441 & 458,
TSIIC-Formulation SEZ, Polepally Village,
Jadcherla (Mandal), Mahaboob Nagar District
Telangana State,
India – 509 301

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in September 2022

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>