

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/prequal/sites/default/files/document_files/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 is for you only. Do not pass it on to others. It may harm them, even if their illness seems 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 an ‘anthelmintic’, a medicine used against parasitic worms. It contains the active substance praziquantel.

[NT011 trade name] can be used to treat the following parasitic worm infections:

- Blood fluke infection (schistosomiasis)
- Tapeworm infections in the intestine (taeniasis)
- Tapeworm infections in the brain (neurocysticercosis)
- Flatworm infections (trematodiasis) that you can catch from some types of food:
 - Liver fluke infections (clonorchiasis and opisthorchiasis)
 - Lung fluke infection (paragonimiasis)

[NT011 trade name] can also be used for community treatment programmes to prevent the following parasitic worm infections:

- Blood fluke infection (schistosomiasis)
- Tapeworm infections in the intestine (taeniasis)
- Liver fluke infections (clonorchiasis and opisthorchiasis)

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

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 tapeworm infection (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 can make [NT011 trade name] treatment less effective.

Take special care with [NT011 trade name]

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

- have liver problems,
- suffer from heart disease, including problems with your heart rhythm,
- have epilepsy or have ever had convulsions (fits),
- have ever had cysticercosis nodules (bumps) under the skin,

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.

Tell your health care provider if you are taking rifampicin (a tuberculosis medicine) because it can stop [NT011 trade name] working well enough.

Taking efavirenz (for treating HIV), carbamazepine, phenytoin and phenobarbital (for treating epilepsy) or dexamethasone (a steroid medicine) with [NT011 trade name] is not recommended.

Other medicines can also have an effect on your treatment 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)
- ritonavir (used to treat HIV infection)

[NT011 trade name] with food and drink

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.

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

Driving and using machinery

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

3. How to take [NT011 trade name]

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

Do not crush or chew [NT011 trade name]. The bitter taste of the tablets is very unpleasant.

Blood fluke worm infection (schistosomiasis) – treatment and prevention

For treating schistosomiasis, your health care provider will use your weight to work out a dose of [NT011 trade name] that is right for you. The usual recommended dose is:

40 mg/kg given as a single dose.

For preventing schistosomiasis in your community, your health care provider may use your height to give you a dose that is right for you. The usual doses are shown in the table below.

Height	Praziquantel dose	
	As 600-mg tablet	In mg of praziquantel
94–109 cm	1 tablet as a single dose	600 mg as a single dose
110–124 cm	1½ tablets as a single dose	900 mg as a single dose
125–137 cm	2 tablets as a single dose	1200 mg as a single dose
138–149 cm	2½ tablets as a single dose	1500 mg as a single dose
150–159 cm	3 tablets as a single dose	1800 mg as a single dose
160–177 cm	4 tablets as a single dose	2400 mg as a single dose
178 cm or taller	5 tablets as a single dose	3000 mg as a single dose

This prevention dose is repeated usually every year (if the infection is very common) until the infection is well controlled.

Take [NT011 trade name] with a meal when it is used to treat schistosomiasis (blood fluke worm infection).

Tapeworm infection (taeniasis) in the intestines – treatment and prevention

For treating taeniasis or for preventing taeniasis in your community, your health care provider will use your weight to work out a dose of [NT011 trade name] that is right for you. The usual recommended dose is:

10 mg/kg given as a single dose.

This prevention dose is also suitable in communities where both blood fluke worm infection and tapeworm infections are common.

Take your dose for treating or preventing tapeworm infection at least 2 hours after a meal and at least 30 minutes before the next meal.

Tapeworm infection in the brain (neurocysticercosis) – treatment

For treating neurocysticercosis, [NT011 trade name] is given with another medicine called albendazole. Your health care provider will use your weight to work out a dose of [NT011 trade name] that is right for you. The usual recommended dose is:

total of 50 mg/kg daily split into 2 or 3 doses.

Treatment is continued for 1–2 weeks but where certain parts of the brain are infected, treatment may need to be continued for 1 month or longer.

Flatworm infections – treatment

For treating liver fluke infection (**clonorchiasis** and **opisthorchiasis**), your health care provider will use your weight to work out a dose of [NT011 trade name] that is right for you. The usual recommended dose is:

25 mg/kg 3 times daily for 2–3 days

For treating lung fluke infection (**paragonimiasis**), your health care provider will use your weight to work out a dose of [NT011 trade name] that is right for you. The usual recommended dose is:

25 mg/kg 3 times daily for 3 days

Flatworm infections – prevention

For preventing liver fluke infection (**clonorchiasis** and **opisthorchiasis**), your health care provider will use your weight to work out a dose of [NT011 trade name] that is right for you. The usual recommended dose is:

40 mg/kg given as a single dose, repeated every 12 months

Doses for children

Your health care provider will decide if very young children should be treated with [NT011 trade name].

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

Your health care provider will normally give you the right amount of medicine so the chances of taking too many tablets is small. Taking too many tablets at once may make you feel unwell.

If you accidentally take too much medicine, tell your health care provider or contact your nearest hospital emergency department for advice.

You may need medical attention. Remember to take the medicine container with you to show to the health care provider.

4. Possible side effects

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

A few people get allergic reactions but serious allergic reactions are rare. If you 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, tell your health care provider.

Very common side effects (these may affect more than 1 in 10 patients treated):

- Headache
- Dizziness
- Abdominal (belly) pain, nausea (feeling sick), or vomiting
- Feeling tired
- Itchy rash

Common side effects (these may affect up to 1 in 10 patients treated):

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

Very rare side effects (these can affect less than 1 in every 10 000 patients treated):

- Allergic reactions
- Increased eosinophils (a type of white blood cell)
- Polyserositis (inflammation of the lining around internal organs)
- Fits (seizures or convulsions)
- Changes to the rhythm of your heart
- Bloody diarrhoea

Side effects may be more frequent 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 a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [NT011 trade name]

Do not store above 30°C. Avoid excursions above 30°C. Store in the original container.

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 after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the 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

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

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

[NT011 trade name] is white to orange tinged, oblong, film-coated tablet. They are biconvex (rounded on top and bottom) with a bevelled edge. The tablets are plain on the other side with three break lines on one side with “P8” debossed (stamped into the tablet) and two scores with “H” debossed (stamped into the tablet) on the other side.

The break line can be used to divide [NT011 trade name] into either two or four equal doses.

HDPE bottle

[NT011 trade name] is provided in a white opaque, HDPE bottle containing 6, 100, 500 or 1000 tablets. The bottle also contains purified cotton as a space filler. The bottle has a white opaque, polypropylene ribbed child resistant plastic cap closure with a pulp liner.

Blister

[NT011 trade name] is provided in a cold form PVC/Alu/OPA-Alu blister, each blister card containing 6 or 10 tablets. Available in packs of 1 x 6 or 10 x 10's tablets.

Supplier and Manufacturer

Supplier

Hetero Labs Limited
Hetero Corporate
7-2-A2, Industrial Estates
Sanath Nagar
Hyderabad
Telangana, 500 018
India
E-mail:contact@heterodrugs.com

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 2024

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>