

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

[NT014 trade name][†]
Albendazole

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 [NT014 trade name] is and what it is used for
2. What you need to know before you take [NT014 trade name]
3. How to take [NT014 trade name]
4. Possible side effects
5. How to store [NT014 trade name]
6. Contents of the pack and other information

1. What [NT014 trade name] is and what it is used for

[NT014 trade name] contains the active substance albendazole. It is used to treat infections caused by some parasites (worms) that usually infect the gut but that can also cause problems in other parts of the body. It works by stopping the worm digesting and using food, so that it starves and dies.

Infections caused by tapeworms

[NT014 trade name] is used to treat *cystic echinococcosis* and *alveolar echinococcosis*, caused by tapeworms that form cysts in the liver, lungs and other parts of the body. The medicine is used before or after surgery, or when surgery is not possible.

[NT014 trade name] is also used to treat *neurocysticercosis*, an infection of the nervous system caused by pork tapeworms.

[NT014 trade name] may sometimes be given in a community programme to stop the spread of tapeworm infections in the gut (*taeniasis*) in people living in areas where the infection is common.

Lymphatic filariasis

[NT014 trade name] is used to stop the spread of the roundworm infection called *lymphatic filariasis* which can cause fever, cough and wheezing, swelling of the lymph nodes, swollen limbs or genitals, and kidney problems. [NT014 trade name] is used together with other medicines as part of a community programme.

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

Other infections caused by roundworms

[NT014 trade name] is effective against several infections caused by roundworms. It can therefore be used, together with other medicines, as part of a community programme to control the spread of the soil-transmitted infections *ascariasis*, *trichuriasis* and *hookworm* (*ancylostomiasis* and *necatoriasis*).

2. What you need to know before you take [NT014 trade name]

Do not take [NT014 trade name] if you are allergic to albendazole or related medicines such as mebendazole, or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your health care provider before taking [NT014 trade name].

Warnings and precautions

Before starting treatment with [NT014 trade name], tell your health care provider about any medical conditions you have. In particular:

- If you have **liver problems**, you must get medical advice before taking this medicine.

[NT014 trade name] may cause liver problems. Speak with your health care provider straightaway if you are taking a course of treatment with this medicine and you:

- lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash
and you have any of the following
 - belly pain, usually on the right side and near the chest
 - unexplained itching
 - yellowing of the white parts of your eyes, your nails or your skin
 - passing dark urine
 - passing stools that are very pale

These are signs of a problem with your liver, which can become serious. Your health care provider may carry out blood tests to check for liver problems.

During treatment with [NT014 trade name] you should also tell your health care provider immediately:

- if you develop **severe headache, nausea and vomiting, fits or problems with your vision**.

These may be signs of swelling in your brain or damage to your eyes and you may need to start appropriate treatment straightaway.

Blood tests

If you are having a longer course of treatment with [NT014 trade name] (usually for the tapeworm infection) your health care provider will test your blood before and during your treatment with [NT014 trade name]. This is to check for liver problems and because [NT014 trade name] may reduce the production of blood cell. Your health care provider may decide to stop your treatment if you develop serious liver problems or your blood cell counts decrease too much.

Other medicines and [NT014 trade name]

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

In particular, tell your health care provider if you are taking:

- Dexamethasone (a corticosteroid)
- Praziquantel (used to treat worm infections)
- Cimetidine (used to treat heartburn)
- Ritonavir (for HIV infection)
- Carbamazepine, phenobarbital, phenytoin, (for epilepsy)

These medicines may affect the action of [NT014 trade name] and your health care provider may need to adjust your treatment.

Pregnancy and contraception

Tell your health care provider if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

There is not enough information to be certain whether [NT014 trade name] might harm an unborn child, especially with a long course of treatment or if you take it in the first 3 months of pregnancy. Therefore, the medicine should not be used during pregnancy unless absolutely necessary. If you are pregnant or think you might be, ask your health care provider for advice about taking your medicine.

It is usually OK to breast feed your baby during treatment with this medicine – ask your health care provider.

If you might get pregnant, ask your health care provider for advice about using effective contraception during a course of treatment; you may need to use contraception for up to 1 month after the end of treatment.

Driving and using machines

[NT014 trade name] is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

Other ingredients of [NT014 trade name]

This medicine contains 0.2 mg benzyl alcohol in each tablet. Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gaspings syndrome”) in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your healthcare provide.

[NT014 trade name] should not be used for more than a week in young children (less than 3 years old), unless advised by the health care provider.

Ask your healthcare provide for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

[NT014 trade name] contains 8 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

[NT014 trade name] contains lactose. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [NT014 trade name]

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

[NT014 trade name] is available as tablets to be taken by mouth.

The tablet can be chewed before swallowing.

Your health care provider will tell you how many tablets you need to take and for how long, depending on the infection you need to treat. The health care provider will also tell you whether to take your dose before food or with meals.

Use in adults

For the tapeworm infections *cystic echinococcosis* and *alveolar echinococcosis* the usual dose of [NT014 trade name] is 1 tablet twice daily. Your health care provider will tell you how long you need to continue treatment, which may be for months or years, depending on where the infection is and what other treatments you are given. Your daily dose may be lower if you weigh less than 60 kg.

For *neurocysticercosis* the usual dose of [NT014 trade name] is 1 tablet twice daily for 10 to 14 days but your health care provider may recommend you take the medicine for longer.

In community programmes to control tapeworms in the gut (*taeniasis*) [NT014 trade name] is given as 1 tablet daily for 3 days.

When [NT014 trade name] is used as part of a community programme to control *lymphatic filariasis* or roundworms in the gut (*ascariasis*, *trichuriasis*, *hookworm*), it is taken as a single tablet once or twice a year.

Use in children

There is limited information on the use of [NT014 trade name] for tapeworm infections in children. In community programmes to control tapeworms in the gut (*taeniasis*) children from 2 years of age may be given 1 tablet of [NT014 trade name] daily for 3 days

For roundworm infections, [NT014 trade name] can be used from the age of 1 year. In children aged 1 to 2 years, the usual dose is half a tablet. In children aged above 2 years, the dose is the same as for adults.

If you take more [NT014 trade name] than you should

If you take too much of the medicine, contact your health care provider straight away for advice. Take your medicine pack and this leaflet with you if you can.

If you forget to take [NT014 trade name]

If you forget to take your dose, take it as soon as you remember.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

[NT014 trade name] may affect your liver and blood cells. This is why you will have blood tests before and during treatment.

Speak with your health care provider straightaway if you are taking a course of treatment with this medicine and you get any signs of **liver problems** (see Section 2, Warnings and precautions, for how to recognise these).

Tell your health care provider if you develop any of the following side effects:

Side effects that can occur when treated with [NT014 trade name] for a short time

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

- belly pain, feeling or being sick

Uncommon side effects: may affect up to 1 in 100 people

- headache, dizziness
- diarrhoea
- itchiness, skin rashes

Rare side effects: may affect up to 1 in 1000 people

- allergic reactions (with signs including rash and itchiness)
- bone pain
- protein in the urine
- blood test showing low red cell count
- blood tests showing raised liver enzymes (sign of stress on the liver)

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

- serious blistering skin rashes with swelling and peeling (erythema multiforme, Stevens-Johnsons syndrome)

Side effects that can occur when treated with [NT014 trade name] for a longer time

Very common: may affect more than 1 in 10 people

- headache
- blood tests showing raised liver enzymes (sign of stress on the liver)

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

- dizziness
- belly pain, feeling or being sick
- temporary thinning of hair and hair loss
- fever

Uncommon side effects: may affect up to 1 in 100 people

- headache, dizziness
- diarrhoea
- itchiness, skin rashes
- hepatitis (inflammation of the liver)
- blood test showing low white cell count
- allergic reactions (with signs including rash, itchiness and urticaria)

Rare side effects: may affect up to 1 in 1000 people

- bone pain
- protein in the urine
- blood test showing low red cell count

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

- serious blistering skin rashes with swelling and peeling (erythema multiforme, Stevens-Johnsons syndrome)
- blood test showing low count of all blood cells

If any side effects get serious or if you notice any side effects not listed in this leaflet, please tell your health care provider.

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 [NT014 trade name]

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

Do not store above 30°C. Avoid excursions above 30°C. Protect from moisture. Discard the product 60 days after initial opening.

Do not use this medicine after the expiry date stated on label 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 [NT014 trade name] contains

- The active ingredient is albendazole 400 mg.
- The other ingredients of [NT014 trade name] are sodium starch glycolate, microcrystalline cellulose, sodium lauryl sulphate, maize starch, colloidal anhydrous silica, aspartame, mixed fruit flavour, purified talc and magnesium stearate.

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

What [NT014 trade name] looks like and contents of the pack

[NT014 trade name] is white to off-white, oblong, uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a break line on one side and are plain on the other side.

[NT014 trade name] is provided in round, white plastic (HDPE) bottle containing 100 tablets. The bottle has an aluminium tagger seal and a round, white childproof plastic (polypropylene) cap.

Supplier and Manufacturer

Supplier

Mepro Pharmaceuticals Pvt. Ltd.
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Manufacturer

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

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