

## **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.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

[NT016 trade name]<sup>†</sup>  
Albendazole

*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 [NT016 trade name] is and what it is used for
2. What you need to know before you take [NT016 trade name]
3. How to take [NT016 trade name]
4. Possible side effects
5. How to store [NT016 trade name]
6. Contents of the pack and other information

#### 1. What [NT016 trade name] is and what it is used for

[NT016 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

[NT016 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.

[NT016 trade name] is also used to treat neurocysticercosis, an infection of the nervous system caused by pork tapeworms.

[NT016 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

[NT016 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. [NT016 trade name] is used together with other medicines as part of a community programme.

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

## Other infections caused by roundworms

[NT016 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 [NT016 trade name]

**Do not take [NT016 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 [NT016 trade name].

## Warnings and precautions

Before starting treatment with [NT016 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.

[NT016 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 [NT016 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 [NT016 trade name] (usually for the tapeworm infection) your health care provider will test your blood before and during your treatment with [NT016 trade name]. This is to check for liver problems and because [NT016 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 [NT016 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 [NT016 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 [NT016 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**

[NT016 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 [NT016 trade name]**

[NT016 trade name] contains lactose, lake of sunset yellow (FD&C yellow #6), benzyl alcohol and sodium benzoate which may cause side effects.

#### ***Benzyl alcohol***

Medicines containing benzyl alcohol should not be given to newborn babies (up to 4 weeks old), unless recommended by a doctor. See section 3 for information on which children can be given [NT016 trade name]. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children.

Do not use [NT016 trade name] for more than a week in young children (less than 3 years old), unless advised by your health care provider.

Ask your health care provider for advice if you are pregnant, breast-feeding or if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in the body and may cause side effects (called “metabolic acidosis”).

Benzyl alcohol may cause allergic reactions.

#### ***Sodium benzoate***

Medicines containing sodium benzoate should not be given to newborn babies (up to 4 weeks old), unless recommended by a doctor. See section 3 for information on which children can be given [NT016 trade name]. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

#### ***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.

#### ***Lake of sunset yellow (FD&C yellow #6)***

The colourant lake of sunset yellow (FD&C yellow #6) may cause allergic reactions.

### **3. How to take [NT016 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.

[NT016 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 [NT016 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 [NT016 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*) [NT016 trade name] is given as 1 tablet daily for 3 days.

When [NT016 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 [NT016 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 [NT016 trade name] daily for 3 days

For roundworm infections, [NT016 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 [NT016 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 [NT016 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.

[NT016 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 [NT016 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 [NT016 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 [NT016 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 light.

Do not use this medicine after the expiry date stated on the carton or blister pack, 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 or 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 [NT016 trade name] contains**

- The active ingredient is 400 mg of albendazole.
- The other ingredients of [NT016 trade name] are lactose monohydrate, microcrystalline cellulose maize starch, croscarmellose sodium, povidone, saccharin sodium, sodium lauryl sulfate, magnesium stearate, colour lake of sunset yellow / FD&C yellow #6, flavour Trusil orange and flavour Trusil vanilla.

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

### **What [NT016 trade name] looks like and contents of the pack**

Light orange, oval, uncoated, mottled 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.

The tablet can be divided into two equal doses.

[NT016 trade name] is available in:

*PVC/PVDC-Alu Blister (plastic/aluminium blister):*

Clear, colourless plastic (PVC/PVDC) on aluminium foil blister cards, each containing 14 tablets. Available in cartons of 4 x 14 tablets.

*Alu/Alu Blister:*

Aluminium foil blister cards, each containing 10 tablets. Available in cartons of 6 x 10 tablets.

## **Supplier**

Indoco Remedies Limited  
166, C.S.T. Road  
Mumbai 400 098  
India

Tel. No. +91 22 2087 3310, +91 22 6278 4200

Email: [asenpal@indoco.com](mailto:asenpal@indoco.com)

## **Manufacturer**

Indoco Remedies Limited  
Unit 1, Village Katha, P.O. Baddi  
Tehsil: Nalagarh, Dist.: Solan  
Himachal Pradesh - 173 205  
India

Tel. No. . +91 22 2087 3310, +91 22 6278 4200

Email: [asenpal@indoco.com](mailto:asenpal@indoco.com)

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

**This leaflet was last revised in January 2025.**

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