

## **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/pqweb/sites/default/files/documents/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

[NT005 trade name]<sup>†</sup>  
Albendazole

**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 [NT005 trade name] is and what it is used for
2. What you need to know before you take [NT005 trade name]
3. How to take [NT005 trade name]
4. Possible side effects
5. How to store [NT005 trade name]
6. Contents of the pack and other information

#### 1. What [NT005 trade name] is and what it is used for

[NT005 trade name] contains the active substance albendazole. It is used to treat infections caused by some parasites (worms) that usually infect the guts but that can also cause problems in other parts of the body. It works by stopping the worm from absorbing sugar, so that the worm loses energy and dies.

#### Infections caused by tapeworms

[NT005 trade name] is used to treat the tapeworm infections called *cystic echinococcosis* (hydatidosis) and *alveolar echinococcosis*, which cause cysts to form in the liver, lungs and other parts of the body. The medicine is used before or after surgery, or when surgery is not possible.

[NT005 trade name] is also used to treat *neurocysticercosis*, an infection of the nervous system caused by pork tapeworms.

#### Lymphatic filariasis

[NT005 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. [NT005 trade name] is used together with other medicines as part of a community programme.

#### Other infections caused by roundworms

[NT005 trade name] is used to treat the following roundworm infections that affect the gut: *ascariasis*, *capillariasis*, *enterobiasis*, *hookworm infections* (necatoriasis and ancylostomiasis), *strongyloidiasis*, *trichostrongyliasis* and *trichuriasis*. It is also used to treat the skin infection *cutaneous larva migrans*, and *trichinellosis* which affect the muscles.

[NT005 trade name] can also 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 infections*.

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<sup>†</sup> 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 [NT005 trade name]

**Do not take [NT005 trade name]** if you are allergic to albendazole 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 [NT005 trade name].

### Warnings and precautions

Before starting treatment with [NT005 trade name], tell your health care provider about all your medical history. In particular:

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

[NT005 trade name] may cause liver problems. Please speak with your health care provider if you get **yellowing of the skin or eyes, dark-coloured urine and/or light coloured stools** during treatment.

During treatment with [NT005 trade name] you should also tell your health care provider immediately:

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

These may be signs of an inflammation within the brain or damage to your eyes and you may need to start appropriate treatment straightaway.

### Blood tests

Your health care provider will test your blood before and during your treatment with [NT005 trade name]. This is because [NT005 trade name] may reduce the production of blood cells by the bone marrow. Your health care provider may decide to stop your treatment if your blood cell counts decrease too much.

### Other medicines and [NT005 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)
- Phenytoin, carbamazepine, phenobarbital (for epilepsy)

These medicines may affect the action of [NT005 trade name] and you may need to change your dose.

### Pregnancy and contraception

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

[NT005 trade name] must not be used during pregnancy unless absolutely necessary, as it might harm your unborn child.

In women who are able to have children, treatment should be started only after a negative pregnancy test.

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

If you are a woman who is able to have children, you must use effective contraception during treatment and for up to 1 month after the end of treatment.

## **Driving and using machines**

Dizziness can occur while taking [NT005 trade name]. If you feel dizzy, do not drive or use any tools or machines.

### *Other ingredients in [NT005 trade name]*

[NT005 trade name] contains lactose

If you have been told by your health care provider that you have an intolerance to some sugars, contact your health care provider before taking this medicinal product.

[NT005 trade name] contains FD&C Yellow #6/Sunset Yellow FCF Aluminium Lake. This may cause allergic reactions.

## **3. How to take [NT005 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.

[NT005 trade name] is available as tablets to be taken by mouth. The tablets may be crushed or swallowed whole with a drink of water.

Your health care provider will tell you the number of tablets you need take and for how long, depending on the infection you need to treat.

### *Use in adults*

For tapeworm (cystode) infections the usual dose of [NT005 trade name] is 1 tablet twice daily in courses of 28 days and then no tablets for 14 days. Your health care provider will tell you how long you need to continue treatment, depending on where the infection is.

For roundworm infections the usual dose is 1 tablet once a day for between 1 to 10 days, depending on the type of infection. Your health care provider may ask you to take [NT005 trade name] twice a day for strongyloidiasis or cutaneous larva migrans.

When [NT005 trade name] is used as part of a community programme to control certain worm infections, it is taken once or twice a year.

### *Use in children*

There is limited information on the use of [NT005 trade name] for tapeworm infections in children.

For roundworm infections, [NT005 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.

For young children or patients not able to swallow the tablets whole, the tablets may be crushed and added to a small amount of semi-solid food or liquid, all of which should be swallowed immediately

## **If you take more [NT005 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 [NT005 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.

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

- yellowing of the skin or eyes, dark-coloured urine or light-coloured stools

These may be signs of liver problems.

[NT005 trade name] may affect your blood cells. This is why you will have blood tests before and during treatment.

The following side effects can occur with [NT005 trade name] treatment for a short period:

**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 1,000 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)

The following side effects can occur with [NT005 trade name] treatment for a longer period:

**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
- 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 1,000 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 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 [NT005 trade name]**

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

Do not store above 30°C. Discard the product 30 days after initial opening.

Do not use this medicine after the expiry date stated on the HDPE bottle, after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

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 [NT005 trade name] contains**

-The active ingredient is albendazole

-The other ingredients of [NT005 trade name] are lactose monohydrate, corn starch, sodium starch glycolate, sodium lauryl sulphate, povidone, microcrystalline cellulose, saccharin sodium, magnesium stearate, colour FD & C yellow #6 (Lake sunset yellow FCF)

### **What [NT005 trade name] looks like and contents of the pack**

[NT005 trade name] is a mottled, pale orange, oblong-shaped biconvex uncoated tablet with a score line on one side and "C541" the other side.

[NT005 trade name] White HDPE bottle with blue child-resistant polypropylene cap, heat seal liner and rayon sani coil.  
Pack size: 60 tablets.

### **Supplier and Manufacturer**

#### ***Supplier***

Cipla Limited  
Cipla House  
Peninsula Business park  
Ganpatrao Kadam Marg  
Lower Parel  
Mumbai 400 013  
India.  
Tel: +91-22-24826000  
Fax: +91-22-24826120  
Email: globalra@cipla.com

#### ***Manufacturer***

Cipla Limited Indore (Unit-IV)  
Plot No 9, 10 & 15  
Indore Special Economic Zone, Phase II  
Pithampur, Dhar District  
Madhya Pradesh 454 775  
India

For any information about this medicine, contact the supplier

**This leaflet was last revised in May 2021**

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