WHO-PQ RECOMMENDED SUMMARY OF PRODUCT CHARACTERISTICS

This summary of product characteristics 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

1. NAME OF THE MEDICINAL PRODUCT

[NT012 trade name]†

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains albendazole 400 mg.

Excipients with potential clinical effect

The tablet contains 150 mg of lactose monohydrate, 1.5 mg of colour lake of sunset yellow/FD&C yellow #6 and 19 mg of dextrose.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable tablets

[NT012 trade name] is pale 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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[NT012 trade name] is a broad-spectrum anthelmintic used for the following infections:

Cestode infections (tapeworms)

[NT012 trade name] is indicated for the treatment of *Echinococcus multilocularis* and *E. granulosus* infections before or after surgery or where surgery is not suitable.

[NT012 trade name] is further indicated for the treatment of neurocysticercosis caused by larval forms of the pork tapeworm, *Taenia solium*.

It may also be given for preventive chemotherapy of *Taenia solium* taeniasis in endemic populations, where other alternatives are not available.

Lymphatic filariasis

[NT012 trade name] is indicated together with ivermectin or diethylcarbamazine, or both, for the elimination of lymphatic filariasis.

Treatment is given to the entire eligible population in endemic areas through a mass drug administration programme.

Other nematode infections (roundworms)

Albendazole is effective for the treatment of various nematode infections. [NT012 trade name] can be used, alone or in combination with other medicines, for the control of soil-transmitted helminthiasis (ascariasis, trichuriasis and hookworm infections) through mass drug administration programmes.

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

4.2 Posology and method of administration

Posology

Cestode infections (tapeworms)

Adults

In adults over 60 kg, the usual dose for treatment of echinococcosis or *Taenia solium* neurocysticercosis is 400 mg twice a day. In adults up to 60 kg, the dose is 10–15 mg/kg daily in 2 divided doses (maximum 800 mg daily).

- For *cystic echinococcosis,* [NT012 trade name] is given alone or combined with percutaneous or open surgical procedures, in which case it may be started 1 to 7 days before the procedure. Treatment is continued for 1 to 6 months or longer, depending on individual risk factors such as the stage and size of the cyst. In case of suspected or confirmed spillage of cyst contents, albendazole is usually continued for 6 to 12 months; praziquantel should also be given for the first 2 to 4 weeks.
- For *alveolar echinococcosis* treatment should be given for at least 2 years and may be continued for many years, reviewed at 2-year intervals.
- For *neurocysticercosis*, treatment with [NT012 trade name] is usually for 10–14 days but can be increased to up to 30 days or more for extraparenchymal cysts (e.g. in the ventricles or subarachnoid space).

Children

Because data on the use of [NT012 trade name] in children for cestode infections are limited, individualised dosage recommendations cannot be made.

Mass drug administration

In mass drug administration programmes for preventive chemotherapy of *taeniasis* where other alternatives are not available, [NT012 trade name] may be given to endemic populations from 2 years of age in a dose of 400 mg daily for 3 consecutive days. Because of the risk of triggering latent neurocysticercosis, a reporting system must be in place with active surveillance and referral of any neurological adverse events.

Nematode infections

For the elimination of *lymphatic filariasis* and the control of *soil-transmitted helminthiasis* (ascariasis, trichuriasis, or hookworm disease), a single oral dose of [NT012 trade name] is normally given once a year in mass treatment programmes. The dose may be given twice a year at 6-monthly intervals, if required, in line with national treatment plans.

For elimination of lymphatic filariasis, [NT012 trade name] is given together with diethylcarbamazine, or ivermectin, or both; the recommended combination depends on whether loaiasis or onchocerciasis are also endemic.

Adults and children aged over 2 years

In adults and children aged over 2 years, the dose of [NT012 trade name] for mass drug administration is a single 400-mg tablet.

Children aged 1–2 years

In children aged 1–2 years, the dose of [NT012 trade name] for the control of soil-transmitted helminthiasis is 200 mg (half a tablet).

[NT012 trade name] is not used in children below 2 years for the elimination of lymphatic filariasis.

Special populations

Renal impairment

No dose adjustment is required.

Hepatic impairment

Caution should be used if [NT012 trade name] is given to patients with liver disease, since albendazole is metabolised by the liver and has been associated with idiosyncratic hepatotoxicity.

Method of administration

Oral use.

The tablet can be chewed before swallowing

[NT012 trade name] should be taken with a meal for *the prevention and treatment of tissue infections* such as echinococcosis, neurocysticercosis and lymphatic filariasis. Taking albendazole with a fatty meal improves its bioavailability and leads to higher blood levels (see section 5.2).

For *treatment of intestinal infections* such as taeniasis or soil-based helminth infections, [NT012 trade name] should be taken at least 2 hours after a meal and 30 minutes before the next meal. This leads to higher intestinal and lower systemic albendazole levels, which is desirable in these conditions.

4.3 Contraindications

Hypersensitivity to the active substance, other benzimidazoles or to any excipients listed in section 6.1.

In the management of cystic echinococcosis, albendazole is contraindicated if the cyst is at risk of rupture.

4.4 Special warnings and precautions for use

Pre-existing neurocysticercosis

Treatment with albendazole may uncover pre-existing neurocysticercosis, particularly in areas where taeniasis is common.

Patients may experience neurological symptoms such as seizures, increased intracranial pressure and focal signs as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may develop rapidly after treatment, and appropriate corticosteroid and anticonvulsant therapy should be given straight away.

Risk of retinal damage in patients with retinal neurocysticercosis

Cysticercosis may, in rare cases, involve the retina. Before starting therapy for neurocysticercosis, the patient should be examined for the presence of retinal lesions. If such lesions are present, the need for anticysticeral therapy should be weighed against the possibility of retinal damage caused by albendazole-induced changes to the retinal lesion.

Hepatic effects

Patients undergoing treatment for echinococcosis should have their liver function tested before the start of treatment and regularly (ideally every 2 weeks) during treatment. Patients with disturbed liver function tests before starting albendazole should be carefully evaluated, since the medicine is metabolised by the liver and has been associated with idiosyncratic hepatotoxicity.

Mild to moderate elevations of liver enzymes have been reported frequently with prolonged albendazole treatment. Enzyme abnormalities are usually reversible on discontinuation of treatment. In prolonged higher-dose albendazole therapy for echinococcosis there have been rare reports of severe hepatic abnormalities such as jaundice and histological hepatocellular damage, which may be irreversible.

If enzymes are significantly increased (greater than twice the upper limit of normal) during treatment, [NT012 trade name] should be discontinued. [NT012 trade name] treatment may be reinstituted when levels have returned to normal limits, but liver function should be monitored frequently during repeat therapy.

Bone marrow suppression

Albendazole can cause bone marrow suppression and therefore blood counts are needed at the start and ideally every two weeks thereafter during treatment for echinococcosis. Patients with liver disease, including hepatic echinococcosis, may be more susceptible to bone marrow suppression leading to pancytopenia, aplastic anaemia, agranulocytosis and leucopenia and therefore warrant closer monitoring of blood counts. Albendazole should be discontinued if clinically significant decreases in blood cell counts occur.

Excipients

[NT012 trade name] contains lactose and dextrose. Patients with congenital lactase deficiency, galactosaemia or glucose-galactose intolerance must not be given this medicine unless strictly necessary. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance in other patients.

This medicinal product also contains the azo colouring agents sunset yellow/ FD&C yellow #6 which may cause allergic reactions.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

4.5 Interaction with other medicinal products and other forms of interaction

Cimetidine, dexamethasone and praziquantel may all increase the plasma concentration of the active metabolite of albendazole, albendazole sulfoxide.

Carbamazepine, phenobarbital, phenytoin and ritonavir may reduce plasma concentrations of the active metabolite of albendazole. The clinical relevance of this is unknown, but may result in decreased efficacy, especially in the treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies.

4.6 Fertility, pregnancy and breastfeeding

Women of childbearing potential

Pregnancy should be avoided in women treated with albendazole. Adequate contraceptive measures should be taken, particularly with prolonged treatment.

Pregnancy

There are no adequate and well-controlled studies of [NT012 trade name] administration in pregnant women. Limited data from inadvertent single-dose administration of albendazole during the first trimester have not demonstrated an increased incidence of congenital anomalies. However, animal studies with albendazole have revealed evidence of teratogenicity in rats and rabbits (see section 5.3), and therefore [NT012 trade name] should be avoided during the first trimester of pregnancy and be used in pregnant women only if there are no alternatives and the potential benefit justifies the potential risk to the fetus.

Breast-feeding

Albendazole and its active metabolite pass into breast milk in very small amounts; it is generally considered compatible with breast-feeding, particularly in single doses.

Fertility

There are no data on the effects of [NT012 trade name] on human male or female fertility.

Animal studies indicate no effects of albendazole on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

[NT012 trade name] is unlikely to affect the ability to drive or operate machinery.

However, patients should be advised to consider if their clinical status, including any undesirable effects of the medicine, allows them to perform skilled tasks safely.

4.8 Undesirable effects

Data from clinical trials and post-marketing surveillance were used to estimate the frequency of adverse events linked to albendazole.

The undesirable effects of albendazole are listed below by body system or organ. Frequencies are defined as follows: very common (at least 1 in 10), common (1 in 100 to 1 in 10), uncommon (1 in 1000 to 1 in 100), rare (1 in 10 000 to 1 in 1000), and very rare (less than 1 in 10 000).

Short duration of treatment

Blood and lymphatic system disorders
Rare Low red cell count

Immune system disorders
Rare Hypersensitivity reactions including rash, pruritus and urticaria

Nervous system disorders
Uncommon Headache, dizziness

Gastrointestinal disorders
Common Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting)
Uncommon Diarrhoea

Hepatobiliary disorders
Rare Elevations of hepatic enzymes

Skin and subcutaneous tissue disorders
Uncommon Itchiness, skin rashes
Very rare Erythema multiforme, Stevens-Johnson syndrome

Musculoskeletal and connective tissue disorders
Rare Bone pain

Renal and urinary disorders
Rare Proteinuria

Longer duration of treatment

Blood and lymphatic system disorders
Uncommon Leucopenia
Rare Low red cell count
Very rare Pancytopenia, aplastic anaemia, agranulocytosis

Immune system disorders
Uncommon Hypersensitivity reactions including rash, pruritus and urticaria

Nervous system disorders
Very common Headache
Common dizziness

Gastrointestinal disorders
Common Gastrointestinal disturbances (abdominal pain, nausea, vomiting)

Hepatobiliary disorders
Very common Mild to moderate elevations of hepatic enzymes
Uncommon Hepatitis[1]

Skin and subcutaneous tissue disorders
Common Reversible alopecia (thinning of hair, and moderate hair loss)
Very rare Erythema multiforme, Stevens-Johnson syndrome

Musculoskeletal and connective tissue disorders
Rare Bone pain

Renal and urinary disorders
Rare Proteinuria

General disorders
Common Fever

[1] With prolonged albendazole treatment for echinococcosis there have also been reports of severe hepatic abnormalities, including jaundice and hepatocellular damage which may be irreversible

Reporting of suspected adverse reactions

Health care providers are asked to report adverse reactions that may be linked to a medicine, to the marketing authorisation holder, or, if available, to the national reporting system. Reports of suspected adverse reactions to a medicine are important for the monitoring of the medicine's benefits and risks.

4.9 Overdose

In case of overdosage, symptomatic therapy and general supportive measures are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anthelmintics, benzimidazole derivatives, ATC code: P02CA03.

Mechanism of action

Albendazole is a benzimidazole derivative that causes degenerative alterations in the tegument and intestinal cells of the parasite and blocks their energy production, ultimately leading to immobilisation and death of the parasite. It works by binding to the colchicine-sensitive site of tubulin, thus inhibiting its assembly into microtubules. As cytoplasmic microtubules are critical in promoting glucose uptake, the glycogen stores of the parasites are depleted.

Albendazole exhibits larvicidal, ovicidal and vermicidal activity against helminth parasites. At lower doses the anthelminthic action of albendazole is thought to be mainly intra-intestinal. However, at higher doses, sufficient is absorbed and metabolised to the active sulfoxide metabolite to have a therapeutic effect against tissue parasites.

A number of studies have suggested that therapeutic doses of benzimidazoles are only parasitostatic against *E. multilocularis*. Nonetheless, after several years of albendazole treatment, treatment interruption may be considered, in the absence of progression of the lesions assessed by conventional imaging, and indirect assessment of viability using PET/CT. Although it does not provide direct evidence of *E. multilocularis* viability, and recurrence may occur, this technique, together with the follow-up of specific serum antibodies, may support decision-making and follow-up after albendazole withdrawal in highly selected patients.

5.2 Pharmacokinetic properties

Absorption of [NT012 trade name]

The absorption characteristics of [NT012 trade name] have been determined in healthy subjects under fed conditions as follows:

Characteristic	**Arithmetic mean ± standard deviation**
Maximum concentration (C_{max})	50 ± 47 ng/mL
Area under the curve ($AUC_{0-\infty}$), a measure of the extent of absorption	207 ± 218 ng·h/mL
Time to attain maximum concentration (T_{max}) [#]	3.08 ± 0.96 hours

#median (range)

Pharmacokinetics of albendazole

General	
	Albendazole concentrations are negligible or undetectable in plasma as it is rapidly converted into the sulfoxide metabolite prior to reaching the systemic circulation. The systemic anthelmintic activity has been attributed to this primary metabolite, albendazole sulfoxide. Maximal plasma concentrations of albendazole sulfoxide are typically achieved 2 to 5 hours after dosing.
Absorption	
Absolute bioavailability	Not available
Oral bioavailability	Albendazole is poorly absorbed from the gastrointestinal tract (< 5%) due to its low aqueous solubility.
Food effect	Absorption is significantly enhanced (approximately 5-fold) if albendazole is taken with a fatty meal. Following a single 400-mg oral dose of albendazole, the maximum plasma concentration of albendazole sulfoxide was 0.4–1.6 μmol/L in fasting patients and 1.8–6.0 μmol/L when taken with breakfast (estimated fat content 40 g).
Distribution	
Volume of distribution (mean)	Not available
Plasma protein binding *in vitro*	Albendazole sulfoxide is 70% bound to plasma protein.
Tissue distribution	Albendazole sulfoxide is widely distributed throughout the body; it has been detected in urine, bile, liver, cyst wall, cyst fluid, and cerebral spinal fluid.
Metabolism	
	Albendazole rapidly undergoes extensive first-pass metabolism in the liver to albendazole sulfoxide, and is generally not detected in plasma. Albendazole sulfoxide is further metabolised to albendazole sulfone and other primary oxidative metabolites.
Active metabolite(s)	Albendazole sulfoxide
Elimination	
Elimination half life	The terminal elimination half-life of albendazole sulfoxide typically ranges from 8 to 12 hours.
Mean systemic clearance (Cl/F)	
Excretion	Following oral administration, albendazole has not been detected in human urine. Albendazole sulfoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine.
Pharmacokinetic linearity	
	Plasma concentrations of albendazole sulfoxide increase in a dose-proportional manner over the therapeutic dose range following ingestion of a fatty meal.

Drug interactions *(in vitro*)	
Transporters	Not available
Metabolising enzymes	Not available

Special populations

Renal impairment

Since renal elimination of albendazole and its primary metabolite, albendazole sulfoxide, is negligible, it is unlikely that clearance of these compounds would be altered in these patients.

Liver impairment

In patients with evidence of extrahepatic obstruction, the systemic availability of albendazole sulfoxide was increased 7-fold.

Elderly patients

Although no studies have investigated the effect of age on albendazole sulfoxide pharmacokinetics, data suggest that the pharmacokinetics are similar to those in young healthy subjects.

Children

Following single-dose administration of 200 to 300 mg (approximately 10 mg/kg) albendazole to paediatric patients with hydatid cyst disease (age range 6 to 13 years), albendazole sulfoxide pharmacokinetics were similar to those observed in fed adults.

5.3 Preclinical safety data

General toxicity

Studies of up to 6 months in mice, rats and dogs recognised the haematopoietic system and the liver as target organs of toxicity.

Genotoxicity

In genotoxicity tests, albendazole was found negative in an Ames Salmonella/microsome plate mutation assay, Chinese hamster ovary chromosomal aberration test, and *in vivo* mouse micronucleus test. In the *in vitro* BALB/3T3 cells transformation assay, albendazole produced weak activity in the presence of metabolic activation while no activity was found in the absence of metabolic activation.

Carcinogenicity

Long-term carcinogenicity studies found no evidence of increased incidence of tumours in mice or rats at up to 400 mg/kg/day and 20 mg/kg/day, respectively.

Effects on reproduction

Albendazole did not affect male or female fertility in the rat at an oral dose level of 30 mg/kg/day.

Albendazole was teratogenic (embryotoxicity and skeletal malformations) in pregnant rats and rabbits. The teratogenic response in the rat occurred at oral doses of 10 and 30 mg/kg/day during gestation days 6 to 15, and in pregnant rabbits at oral doses of 30 mg/kg/day during gestation days 7 to 19. In the rabbit study, maternal toxicity (33% mortality) occurred at 30 mg/kg/day. In mice, no teratogenic effects were observed at oral doses up to 30 mg/kg/day administered during gestation days 6 to 15.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium

Colour lake of sunset yellow / FD&C yellow #6

Lactose monohydrate

Maize starch

Magnesium stearate

Microcrystalline cellulose

Orange flavourant

Polysorbate 80

Povidone

Saccharin sodium

Sodium lauryl sulfate

This medicine is essentially 'sodium-free'. It contains less than 1 mmol sodium (23 mg) per tablet.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

In-use period

Discard the product 28 days after initial opening.

6.4 Special precautions for storage

Do not store above 30ºC. Protect from light.

6.5 Nature and contents of container

HDPE container:

[NT012 trade name] is provided in a rectangular, opaque white plastic (HDPE) pot containing 1000 and 100 tablets. The tablets are packed in a sealed transparent plastic (polyethylene) bag inside the pot. It also contains a sachet of desiccant (drying material). The pot has an aluminium foil seal and a white plastic (HDPE) screw cap.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. SUPPLIER

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8. WHO REFERENCE NUMBER (WHO Prequalification Programme)

NT012

9. DATE OF PREQUALIFICATION

25 December 2024

10. DATE OF REVISION OF THE TEXT

January 2026

References

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