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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

1. NAME OF THE MEDICINAL PRODUCT

[NT007 trade name]†

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 3 mg ivermectin.

For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
Round, white tablet with no marks, of approximately 5mm in diameter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[NT007 trade name] is indicated for the following helminthiases and ectoparasitic infestations:

Filarial infections

[NT007 trade name] is indicated for treatment and elimination of onchocerciasis.

[NT007 trade name] is also indicated together with albendazole for control of microfilaraemia and elimination of lymphatic filariasis in countries in which onchocerciasis is also present. Where onchocerciasis and loaiasis are not endemic, [NT007 trade name] may be used with albendazole and diethylcarbamazine.

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

Strongyloidiasis and soil-transmitted helminthiases

[NT007 trade name] is indicated for the treatment of intestinal (non-disseminated) strongyloidiasis.

[NT007 trade name] may be used with albendazole, including as part of mass drug administration programmes for the treatment of other soil-transmitted intestinal worm infections.

Scabies

[NT007 trade name] is indicated for the treatment of severe or crusted scabies. It is also indicated for mild or moderate scabies when topical treatments are ineffective or cannot be used.

4.2 Posology and method of administration

Posology

Filarial infections

A single oral dose of ivermectin is normally given once a year in mass treatment programmes for onchocerciasis and lymphatic filariasis. Doses are based on the patient's height as follows:

Height	Dose
90 to 119 cm	1 tablet (3 mg) as a single dose
120 to 140 cm	2 tablets (6 mg) as a single dose
141 to 159 cm	3 tablets (9 mg) as a single dose
More than 159 cm	4 tablets (12 mg) as a single dose

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

For treatment of onchocerciasis, the dose may be given twice a year at 6-monthly intervals, if required, in line with national treatment plans.

Alternatively, doses for the treatment of onchocerciasis may be calculated based on the patient's weight, in order to provide a dose of approximately 150 micrograms/kg:

Weight	Dose
15–25 kg	1 tablet (3 mg) as a single dose
26–44 kg	2 tablets (6 mg) as a single dose
45–64 kg	3 tablets (9 mg) as a single dose
Over 64 kg	4 tablets (12 mg) as a single dose

For the community suppression of lymphatic filariasis, [NT007 trade name] should be given with albendazole, or alternatively, in areas in which onchocerciasis is not endemic, with albendazole and diethylcarbamazine citrate, according to national treatment plans.

Strongyloidiasis and soil-transmitted helminthiases

The recommended dose, based on ivermectin 200 micrograms/kg as a single dose, is shown in the following table:

Weight	Dose
15 to 24 kg	1 tablet (3 mg) as a single dose
25 to 35 kg	2 tablets (6 mg) as a single dose
36 to 50 kg	3 tablets (9 mg) as a single dose
51 to 65 kg	4 tablets (12 mg) as a single dose
66 to 79 kg	5 tablets (15 mg) as a single dose
Over 80 kg	6 tablets or more (to give a dose of 200 micrograms/kg)

When added to mass drug administration programmes for controlling soil-transmitted helminthiases, [NT007 trade name] should be given with albendazole.

Scabies

For the treatment of severe and crusted scabies in adults and children weighing at least 15 kg [NT007 trade name] is recommended in an oral dose of 200 micrograms/kg body weight, repeated once after 1 to 2 weeks.

For mild to moderate scabies a dose of [NT007 trade name] 200 micrograms/kg may be given if topical treatment with permethrin is ineffective or not feasible.

Hygiene measures to prevent reinfection must be also be followed and clothes, towels and bedding should be thoroughly cleaned using hot water, subjected to heat using an iron or clothes drier, or placed inside sealed bags for at least a week to ensure that any mites present have died.

Household members and close contacts should also be treated.

Paediatric population

The safety of ivermectin in children weighing less than 15 kg (roughly corresponding to a height below 90 cm) has not been established and treatment is not recommended in this group.

Method of administration

Oral route. The tablets should be taken with water on an empty stomach.

The dose may be taken at any time of the day, but no food should be taken within two hours before or after administration, as the influence of food on absorption is unknown.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Ivermectin is not a prophylactic therapy for filarial infection or strongyloidiasis. It has not been shown to be effective in killing adult filariae.

Ivermectin does not have any beneficial effect on tropical pulmonary eosinophilia syndrome, on lymphadenitis or on lymphangitis associated with filarial infections.

Ivermectin should not be given to patients who are seriously ill. An assessment of health status is recommended before treatment to exclude seriously ill individuals.

Loaiasis

Following administration of ivermectin, the intensity and severity of adverse effects are probably related to the pre-treatment microfilarial density. In patients co-infected with *Loa loa*, microfilarial density, particularly in the blood, is most often high which predisposes the treated patients to an increased risk of serious adverse effects.

CNS adverse effects (encephalopathies) have been reported in rare cases in patients treated with ivermectin and co-infected by a high number of microfilariae of *Loa loa* (see section 4.8). Consequently, in *Loa loa* endemic areas, ivermectin is not recommended as part of programmes to treat lymphatic filariasis and special measures should be taken before any onchocerciasis treatment with ivermectin.

Mazzoti reaction

Following administration of medicines with a rapid microfilaricidal action in patients with onchocerciasis, cutaneous and systemic reactions of varying severity (the Mazzotti reaction), and ophthalmological reactions have been reported. These reactions are probably due to inflammatory responses to degradation products released by the death of microfilariae. Patients treated with ivermectin for onchocerciasis may also experience these reactions when treated for the first time.

Patients with hyperreactive onchodermatitis or “sowda” (observed particularly in Yemen) are more likely than others to experience severe cutaneous adverse reactions (oedema and aggravation of onchodermatitis) after treatment with microfilaricidal medicines.

Immunocompromised patients

Efficacy and dosing regimen of ivermectin in immunocompromised patients with intestinal strongyloidiasis have not been established by adequate clinical studies. There have been cases which show the persistence of infestation following a single dose of ivermectin, particularly in this type of patient.

Children

Ivermectin is not recommended for use in children less than 90 cm tall or weighing less than 15 kg.

Pregnancy and breast-feeding

Ivermectin should not be used during pregnancy or in lactating women for the first week after birth (see section 4.6).

4.5 Interaction with other medicinal products and other forms of interaction

Interactions between ivermectin and other medicines have not been studied in clinical trials.

There have been rare post-marketing reports of increased INR (International Normalised Ratio) when ivermectin was given with warfarin.

4.6 Fertility, pregnancy and breastfeeding

Pregnancy

There are no adequate and well-controlled studies of [NT007 trade name] administration in pregnant women. Animal studies have revealed evidence of teratogenicity (see section 5.3). Ivermectin should only be used when strictly indicated.

Breastfeeding

Ivermectin passes into human milk in low concentrations. Treatment of mothers who intend to breast-feed should only be undertaken when the risk of delayed treatment to the mother outweighs possible risk to the newborn.

In mass administration programmes for community suppression, women who are breast-feeding should not be given ivermectin during the first week after giving birth.

Fertility

No human data on the effect of ivermectin on fertility are available. Ivermectin had no adverse effects on the fertility in rats (see section 5.3).

4.7 Effects on ability to drive and use machines

The effect of [NT007 trade name] on the ability to drive and use machines has not been studied. Some patients may get side effects such as dizziness, somnolence, vertigo and tremor, which could affect the ability to drive or use machines (see section 4.8). Patients should be advised not to drive or operative machines until any such effects have resolved.

4.8 Undesirable effects

Transient eosinophilia, liver dysfunction (hepatitis), increased liver enzymes, hyperbilirubinemia and haematuria have been reported.

Very rarely, toxic epidermal necrolysis and Stevens-Johnson syndrome have also been reported.

Filarial infections

Ivermectin is generally well-tolerated in the management of onchocerciasis. Side effects are related to the parasite density and are mild and transient in most cases, but their severity may be increased in patients infected with more than one parasite, particularly in the case of infestation with *Loa loa*.

Following administration of ivermectin, Mazzotti-type hypersensitivity reactions due to microfilarial death have been reported: pruritus, urticarial rash, conjunctivitis, arthralgia, myalgia (including abdominal myalgia), fever, oedema, lymphadenitis, adenopathies, nausea, vomiting, diarrhoea, orthostatic hypotension, vertigo, tachycardia, asthenia, headache. Rarely, these side effects can be severe. A few cases of asthma exacerbation have occurred.

Abnormal sensation in the eyes, eyelid oedema, anterior uveitis, conjunctivitis, limbitis, keratitis and chorioretinitis or choroiditis can also occur occasionally, but may also be due to the disease itself. They generally resolved without corticosteroid treatment.

In clinical trials involving 963 adults with onchocerciasis given ivermectin 100–200 micrograms/kg, reactions were reported with the following frequency in the first few days after treatment:

Adverse reaction[a]	Ivermectin	Placebo
Pruritus	27.5%	17.2%
Rash including urticarial rash	22.7%	9.2%
Fever	22.6%	4.8%
Lymph node enlargement - axillary	11.0%	2.9%
- cervical	5.3%	4.1%
- inguinal	12.6%	6.7%
- other	3.0%	1.6%
Lymph node tenderness - axillary	4.4%	1.0%
- cervical	1.2%	0.6%
- inguinal	13.9%	5.7%
- other	1.9%	0.6%
Arthralgia/synovitis	9.3%	4.4%
Limbitis	5.5%	6.2%
Punctate opacity	1.8%	2.0%
Peripheral oedema	3.2%	0.6%
Facial oedema	1.2%	0.0%
Tachycardia	3.5%	0.6%
Orthostatic hypotension	1.1%	0.0%

a The most common adverse effects reported in these trials, regardless of causality, were headache (22.3%) and myalgia (19.7%) but headache and myalgia assessed as related to treatment occurred in less than 1% of patients given ivermectin.

Rarely, severe and potentially fatal encephalopathy can occur after administration of ivermectin, particularly in patients also heavily infected with *Loa loa*. In these patients, the following adverse reactions have also been reported: back or neck pain, ocular hyperaemia, subconjunctival haemorrhage, dyspnoea, urinary and faecal incontinence, difficulty in standing or walking, mental status changes, confusion, lethargy, stupor or coma (see section 4.4).

Onset of conjunctival haemorrhage has been reported post-marketing in patients with onchocerciasis.

In the treatment of lymphatic filariasis, the following have occurred: fever, headache, asthenia, feeling of weakness, myalgia, arthralgia, diffuse pain, digestive disorders such as anorexia, nausea, abdominal and epigastric pain, cough, feeling of respiratory discomfort, sore throat, orthostatic hypotension, chills, vertigo, profuse sweating, testicular pain or feeling of discomfort.

Strongyloidiasis

In studies in patients receiving ivermectin for the treatment of strongyloidiasis, dizziness (2.8%), pruritus (2.8%), diarrhoea and nausea (both 1.8%) have been reported commonly; vomiting, constipation, anorexia, abdominal pain, asthenia or fatigue, somnolence, vertigo, tremor, and leucopenia and anaemia were reported in less than 1% of patients.

Scabies

In patients with scabies, pruritus may be exacerbated at the start of treatment. Patients should be warned that itching may persist for one to two weeks after treatment, even if the mite is successfully eradicated. Other reported reactions are uncommon (<1%) and include headache (< 1%), arthralgia (< 1%) and anorexia as

well as lethargy, listlessness, abdominal discomfort, rash, and dizziness. Adult *Ascaris* expulsion has been observed following ingestion of ivermectin.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care providers are asked to report any suspected adverse reactions to the marketing authorisation holder, or, if available, via the national reporting system.

4.9 Overdose
Cases of accidental overdose with ivermectin have been reported, but none have resulted in fatalities.

In cases of accidental intoxication with unknown doses of products destined for veterinary use (oral use, as an injection, cutaneous use), the symptoms were: rash, contact dermatitis, oedema, headache, vertigo, asthenia, nausea, vomiting, diarrhoea and abdominal pain. Other effects include: seizures, ataxia, dyspnoea, paraesthesia and urticaria.

Management has been with symptomatic treatment and surveillance in a medical care setting with fluid replacement and blood pressure management, if necessary. Although there are no specific studies available, it is advisable to avoid GABA agonists in the treatment of accidental intoxication with ivermectin.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Anthelmintics, ATC code: P02CF01.

Ivermectin is derived from avermectins isolated from fermentation broths of *Streptomyces avermitilis*. It has high affinity for glutamate-gated chloride channels in invertebrate nerve and muscle cells. Its binding to these channels promotes an increase in membrane permeability to chloride ions, leading to hyperpolarisation of the neural or muscle cell. This results in neuromuscular paralysis and may lead to the death of certain parasites.

Ivermectin also interacts with other ligand-gated chloride channels such as the one involving the GABA (gamma-aminobutyric acid) neurotransmitter. Mammals do not have glutamate-gated chloride channels. Avermectins have only low affinity for other ligand-gated chloride channels. They do not readily cross the blood–brain barrier.

Filarial infections
Ivermectin is effective in reducing microfilaraemia in patients with onchocerciasis (infection with the filiarial nematode *Onchocerca volvulus*) or lymphatic filariasis (due to Wuch*ereria bancrofti*, *Brugia malayi* or *Brugia timori*). This interrupts community transmission of the infection by vector insects; however, it does not kill adult worms and repeated community treatment is necessary to eliminate infections in endemic areas.

The evaluation of ivermectin in the treatment of onchocerciasis is based on clinical studies involving 1278 patients. In a double-blind, placebo-controlled study involving adults with moderate to severe onchocercal infection, patients who received a single dose of 150 micrograms/kg ivermectin experienced an 83.2% and 99.5% decrease in skin microfilaria count (geometric mean) 3 days and 3 months after the dose, respectively. A marked reduction of > 90% was maintained for up to 12 months after the single dose. As with other microfilaricidal drugs, the microfilaria count increased in the anterior chamber of the eye at day 3 after treatment in some patients. However, at 3 and 6 months after the dose, a significantly greater percentage of patients treated with ivermectin had lower microfilaria count in the anterior chamber than patients receiving placebo.

In a separate open study involving paediatric onchocerciasis, 103 patients aged 6 to 13 (weight range: 17 to 41 kg), similar decreases in skin microfilariae counts were observed for up to 12 months after dosing.

WHO guidelines for elimination of lymphatic filariasis recommend administration of ivermectin with albendazole or with albendazole and diethylcarbamazine citrate, depending on the setting and co-endemicity of onchocerciasis and loaiasis.

Multiple clinical studies conducted in Africa, Asia, South America, the Caribbean and Polynesia reveal a reduction (to less than 1%) in *W. bancrofti* microfilaraemia in the week following an oral ivermectin dose of at least 100 micrograms/kg. These studies showed a dose-dependent effect on time during which the reduction in microfilaraemia and the infestation rate in the populations treated is maintained.

A randomised controlled study involving adults infected with *W. bancrofti* found that complete microfilaraemia clearance was significantly greater 12 months after treatment in 38 patients given ivermectin combined with diethylcarbamazine citrate and albendazole (IDA) than in 43 given ivermectin and albendazole (IA) only (RR: 2.98; 95% CI: 1.74–5.12). The absolute risk estimate indicates that for every 1000 people with microfilaraemia treated, 507 more would experience microfilaraemia clearance 12 months after IDA treatment than with IA treatment. A second study comparing IDA with treatment with diethylcarbamazine citrate and albendazole (DA) found that at 24 months a single dose of IDA resulted in complete clearance of microfilaraemia in 52 of 54 participants (96%), compared with 31 of 55 (56%) and 42 of 56 (75%) given 1 or 2 doses of DA.

Strongyloidiasis

Treatment with a single ivermectin dose of 200 micrograms/kg body weight was effective and well-tolerated in patients with normal immunity and in whom infestation by *Strongyloides stercoralis* is restricted to the digestive tract.

Two controlled clinical studies using albendazole as the comparator were carried out in various countries where albendazole is approved for the treatment of strongyloidiasis of the gastrointestinal tract, and three controlled studies were carried out in the USA and other countries using thiabendazole as the comparative agent. Efficacy, as measured by cure rate, was defined as the absence of larvae in at least two follow-up stool examinations 3 to 4 weeks post-therapy. Based on this criterion, efficacy was significantly greater for ivermectin (a single dose of 170 to 200 micrograms/kg) than for albendazole (200 mg twice daily. for 3 days). Ivermectin as a single dose of 200 micrograms/kg for 1 day was as efficacious as thiabendazole 25 mg/kg twice daily for 3 days.

	Cure rate*	
	Ivermectin†	**Comparator**
		Albendazole‡
International Study	24/26 (92%)	12/22 (55%)
WHO Study	126/152 (83%)	67/149 (45%)
		Thiabendazole∞
International Study	9/14 (64%)	13/15 (87%)
US Studies	14/14 (100%)	16/17 (94%)

* Number (%) of evaluable patients
† 170-200 micrograms/kg
‡ 200 mg twice daily for 3 days
∞ 25 mg/kg twice daily for 3 days

Scabies

A systematic review of 15 studies involving 1896 participants with scabies found that after one week of treatment with oral ivermectin at a standard dose of 200 micrograms/kg or one application of permethrin 5% lotion, there is probably little or no difference in complete clearance rates (illustrative cure rates: permethrin 73%, ivermectin 68%; RR 0.93, 95% CI 0.74 to 1.17). Similarly, illustrative clearance rates compared with permethrin 5% cream were also comparable after 2 weeks (68% with ivermectin, 74% with permethrin).

5.2 Pharmacokinetic properties

Absorption of [NT007 trade name]

The absorption characteristics of [NT007 trade name] have been determined after administration of one (1) tablet in healthy volunteers in the fasted state as follows:

Pharmacokinetic variable	**Arithmetic mean ±standard deviation (*)**
	Ivermectin
Maximum concentration (C_{max})	16.5 ± 5.9 (16.3) ng/mL
Area under the curve ($AUC_{0-\infty}$), a measure of the extent of absorption	374 ± 144 ng.h/mL
Time to attain maximum concentration (t_{max})	4.38 ± 1.24 h

*geometric mean

Pharmacokinetics of ivermectin

General	
	Ivermectin contains 2 components, H2B1a and H2B1b, of which H2B1a is the major component (> 90%).
Absorption	
Absolute bioavailability	NA
Oral bioavailability	NA
Food effect	Administration with a high-fat meal results in approximately 2.5-fold increase in bioavailability relative to the fasted state.
Distribution	
Volume of distribution (mean)	NA
Plasma protein binding	NA
Tissue distribution	NA
Metabolism	
	Metabolised in the liver, mainly by CYP3A4, and possibly to a lesser extent by CYP2D6 and CYP2E1.
Active metabolite(s)	NA
Elimination	
Elimination half life	~18 h
Mean systemic clearance (Cl/F)	NA
% of dose excreted in urine	<1%
% of dose excreted in faeces	99%
Pharmacokinetic linearity	The plasma concentration increases with increasing doses in a generally proportional manner.
Drug interactions *(in vitro)*	
Transporters	NA
Metabolizing enzymes	Studies suggest that ivermectin at standard oral doses does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP1A6 or CYP2E1.

NA: information not available

Hepatic and renal impairment

The pharmacokinetics of ivermectin has not been studied in patients with impaired hepatic or renal function.

5.3 Preclinical safety data

General toxicity

Studies in animals showed that the main effects of ivermectin were attributed to its effects on the central nervous system (mydriasis, tremors, ataxia, anorexia).

Genotoxicity

Ivermectin was not genotoxic in vitro in the Ames microbial mutagenicity assay of *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100 with and without rat liver enzyme activation, the Mouse Lymphoma Cell Line L5178Y (cytotoxicity and mutagenicity) assays, or the unscheduled DNA synthesis assay in human fibroblasts.

Carcinogenicity

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of ivermectin.

Reproductive toxicity

Ivermectin had no adverse effects on the fertility in rats in studies at repeated doses of up to 3 times the maximum recommended human dose of 200 micrograms/kg (on a mg/m^2/day basis).

Ivermectin has been shown to be teratogenic in mice, rats, and rabbits when given in repeated doses of 0.2, 8.1, and 4.5 times the maximum recommended human dose, respectively (on a mg/m^2/day basis). Teratogenicity was characterized in the three species tested by cleft palate; clubbed forepaws were additionally observed in rabbits. These developmental effects were found only at or near doses that were maternotoxic to the pregnant female. Therefore, ivermectin does not appear to be selectively fetotoxic to the developing fetus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Microcrystalline cellulose
Pregelatinized starch
Citric acid
Butylhydroxyanisole (E 320)
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Blister pack

Do not store above 30ºC. Avoid excursions above 30ºC.

Bottle pack

Do not store above 30ºC. Avoid excursions above 30ºC. Keep the HDPE bottle tightly closed in order to protect from light.

6.5 Nature and contents of container

Blister pack

Aluminium-Aluminium blister cards containing either 1 or 10 tablets, each blister card is packed in an outer carton. Pack size: 1 and 10 tablets.

Bottle pack

White HDPE bottle with white polypropylene screw cap. The screw cap also contains a capsular desiccant. Pack size: 250 tablets.

6.6 Special precautions for disposal

Not applicable

7. SUPPLIER

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8. WHO REFERENCE NUMBER (WHO Prequalification Programme)

NT007

9. DATE OF PREQUALIFICATION

01 July 2021

10. DATE OF REVISION OF THE TEXT

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Section 4.6 and 5.3

International Programme on Chemical Safety

Produced on behalf of the World Health Organization (WHO), International Labour Organisation (ILO), and United Nations Environment Programme (UNEP).

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The Reproductive Toxicology Center. REPROTOX®: https://reprotox.org/contact.

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