PROFESSIONAL INFORMATION – YOMESAN CHEWABLE TABLETS

Bayer (Pty) Ltd	**Date of revision of text: 17 January 2022**

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

YOMESAN 500 mg chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains 500 mg niclosamide.
Sugar free
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet
A grey-yellow, round tablet with FE printed on one side and the Bayer cross on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

YOMESAN is indicated for the treatment of the following tapeworm infections in adults and children:

- Infection by *Taenia saginata* (beef tapeworm)
- Infection by *Taenia solium* (pork tapeworm)
- Infection by *Diphyllobothrium latum* (fish tapeworm)
- Infection by *Hymenolepis nana* (dwarf tapeworm)

4.2 Posology and method of administration

Posology

Infections	**Patient group**	**Chewable tablets per day**	
		Day 1	**Day 2 to 7**
Taenia saginata *Taenia solium* *Diphyllobothrium latum*	Children aged above 6 years and adults	4 chewable tablets	Not applicable
	Children aged between 2 and 6 years	2 chewable tablets	Not applicable
	Children aged below 2 years	1 chewable tablet	Not applicable
Hymenolepis nana	Children aged above 6 years and adults	4 chewable tablets	2 chewable tablets per day
	Children aged between 2 and 6 years	2 chewable tablets	1 chewable tablet per day
	Children aged below 2 years	1 chewable tablet	1/2 chewable tablet per day

Special Populations

Patients with hepatic impairment

Niclosamide is not absorbed appreciably from the gastrointestinal tract and does not affect hepatic function. Therefore, dosing adjustment is not required in hepatic impairment.

Patients with renal impairment

Niclosamide is not absorbed appreciably from the gastrointestinal tract and does not affect normal renal function. Therefore, dosing adjustment is not required in renal impairment.

Children

For young children, the chewable tablets should be crushed to a fine paste and given with a little water.

Method of administration

For oral use.
The daily dose is taken as a single dose after breakfast. The pleasant tasting tablets should be thoroughly chewed to a fine paste and washed down with a little water. They can also be taken crushed in water.

Special monitoring advice

Elimination of the intestinal mucus produced abundantly in a tapeworm infection can be promoted by drinking acidic fruit juice, which allows easier access of the product to worms situated underneath the mucus.

If constipated, regular bowel movements should always be established before treatment with YOMESAN. No special dietary measures are necessary.

A saline laxative (e.g., sodium sulphate, magnesium sulphate) can be given two hours after taking the YOMESAN dose (or in the case of *Hymenolepis nana*, after the last dose) to ensure a rapid and complete expulsion of the worm. Without purgation, the parasite is excreted in pieces for about 2 days after the end of treatment.

In the case of Taenia solium (pork tapeworm) infections, a saline laxative is imperative.

4.3 CONTRAINDICATIONS

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

4.4 Special warnings and precautions for use

YOMESAN has no systemic therapeutic effects. It works by eliminating tapeworms present in the intestine. Through elimination of tapeworms, it may have an effect on cysticercosis, or echinococcosis caused by larvae (cysts) of *T. solium, E. ultilocularis or E. granulosus* by preventing their establishment extraintestinally in the tissue.

The risk of cysticercosis existing in cases of pork tapeworm infestation is avoided by the recommended saline laxative purging, the aim being to excrete as quickly as possible the lower tapeworm segments containing the ripe eggs. This prevents the eggs being later transferred to the fingers as a result of deficient defaecation hygiene and from the fingers into the mouth of the patient, where they can cause cysticercosis.

4.5 Interaction with other medicines and other forms of interactions

Niclosamide is soluble in alcohol which may enhance its absorption.
Therefore, YOMESAN should not be taken together with any alcohol-containing beverage (see section 4.7).

4.6 Fertility, pregnancy and lactation

Pregnancy
During pregnancy, and especially during the first trimester, YOMESAN should be used only where it is strictly indicated.

Lactation
It is unknown whether niclosamide is excreted in human breast milk. YOMESAN should only be used in breast-feeding woman after risk/benefit evaluation by a healthcare professional.

4.7 Effects on the ability to drive and use machines

YOMESAN may result in an impairment of the patient's ability to drive or operate machinery due to central nervous system reactions (see section 4.8).

4.8 Undesirable effects

The listed adverse reactions are based on spontaneous reports, and their frequencies are therefore unknown.

Immune system disorders
Allergic reaction (e.g., with erythema, pruritus and exanthema), anaphylactic reaction and anaphylactic shock.

Nervous system disorders
Dizziness (light-headedness)

Vascular disorders
Cyanosis

Gastrointestinal disorders

Nausea, vomiting, gastrointestinal and abdominal pains, retching and diarrhoea

Skin and subcutaneous tissue disorders
Rash, pruritus and hyperhidrosis

General disorders and administration site conditions
Feeling unwell (fatigue)

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the risk/benefit balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 OVERDOSE

According to available evidence, the active substance of YOMESAN, niclosamide, is only slightly absorbed, so that toxic effects are not expected. Should a patient have taken a marked overdosage, for safety reasons the usual therapeutic measures for the treatment of poisoning should be applied (symptomatic therapy).
No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Salicylic acid derivative,
ATC code: P02DA01

Mechanism of action

Niclosamide acts locally by direct contact with the tapeworm's scolex. Niclosamide inhibits oxidative phosphorylation in the parasite's mitochondria, resulting in death of the scolex and adjoining segments. The segment chain then loses its grip and is eliminated from the intestine during bowel movement, either as a whole or in individual small parts.

5.2 Pharmacokinetics properties

Niclosamide is poorly absorbed.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of systemic toxicity, genotoxicity, and reproductive toxicity (embryotoxicity) at therapeutic use.

Carcinogenicity studies with niclosamide were not performed while studies in rats and mice with the ethanolamine salt of niclosamide did not reveal a carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Maize starch.
Talc.
Sodium lauryl sulphate.
Povidone.
Vanillin.
Magnesium stearate.
Saccharin sodium.

6.2 Incompatibilities
Not applicable

6.3 Shelf Life
60 months

6.4 Special precautions for storage

CAUTION: DO NOT REMOVE FROM FOIL UNTIL IMMEDIATELY BEFORE ADMINISTRATION.

Keep out of the reach of children. Store at or below 30 °C.

6.5 Nature and contents of container

Carton containing aluminium blisters consisting of:
Foil 25/45/60 µm PA/Al/PVC (0213), sealed with
Foil 20 µm Al sealable to PVC/PVDC (0201)

Each pack contains 4 tablets or 100 tablets
Pack size of 4's or 100's chewable tablets.
Not all pack sizes may be marketed

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product.
Not Applicable

7. HOLDER OF CERTIFICATE OF REGISTRATIONS

Bayer (Pty) Ltd
Reg. No. 1968/011192/07
27 Wrench Road
Isando

Bayer (Pty) Ltd	**Date of revision of text: 17 January 2022**

1609

8. REGISTRATION NUMBER
H890 (Act 101/1965)
9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Not applicable, Old medicine

10. **DATE OF REVISION OF THE TEXT**

To be allocated