SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

YOMESAN® tablets

COMPOSITION

Each tablet contains 500 mg niclosamide.

The excipients are: maize starch, talcum, sodium lauryl sulphate, povidone, vanillin, magnesium stearate, saccharin sodium.

PHARMACOLOGICAL CLASSIFICATION

A.12 Anthelmintics

PHARMACOLOGICAL ACTION

Pharmacodynamics

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.

Pharmacokinetics

Niclosamide is poorly absorbed.

INDICATIONS

Infestation with:

Taenia saginata (beef tapeworm)

Taenia solium (pork tapeworm)

Diphyllobothrium latum (fish tapeworm)

Hymenolepis nana (dwarf tapeworm)

CONTRA-INDICATIONS

Hypersensitivity to niclosamide or any other constituent of the tablet.

WARNINGS

YOMESAN has no systemic therapeutic effects.

INTERACTIONS

None

PREGNANCY AND LACTATION

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

DOSAGE AND DIRECTIONS FOR USE

The daily dose is taken as a single dose after breakfast. It is very important that the palatable tablets are thoroughly chewed and then washed down with a little water. The tablets may also be taken disintegrated in a little water. For small children it is advisable to grind the tablets as finely as possible and mix the powder with a little water.

In infestation with beef tapeworm (*T. saginata*), pork tapeworm (*T. solium*) and fish tapeworm (*D. latum*):

Adults and children from 6 years upwards	-	4 tablets
Children from 2 – 6 years	-	2 tablets
Children under 2 years	-	1 tablet

For infections with the dwarf tapeworm (*H. nana*), the following treatment for 7 days is recommended:

First day:

Adults and children from 6 years upwards	-	4 tablets
Children from 2 – 6 years	-	2 tablets
Children under 2 years	-	1 tablet

For another six days:

Adults and children from 6 years upwards	-	2 tablets daily
Children from 2 – 6 years	-	1 tablet daily
Children under 2 years	-	$^1/_2$ tablet daily

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

If constipated, thorough cleansing of the bowels is necessary before treatment. Dietetic measures are not necessary.

A drastic saline purge (e.g. sodium sulphate, magnesium sulphate), given two hours after the YOMESAN dose should 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*, a drastic purge is imperative.

Additional information:

The risk of cysticercosis existing in cases of pork tapeworm infestation is avoided by the recommended drastic 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.

YOMESAN may be given safely to patients with liver, biliary and kidney diseases.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

YOMESAN may cause disturbances of the gastro-intestinal tract such as nausea, retching and abdominal pain.
Hypersensitivity reactions (e.g. erythema, pruritus, and exanthema) have been reported.

Ability to drive and use machines
Even when taken in accordance with the instructions this medicine can affect the speed of reaction to such an extent that the ability to drive or operate machinery is impaired. This applies particularly in combination with alcohol.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
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 (gastric lavage, symptomatic therapy).

IDENTIFICATION
A creamy-yellow vanilla flavoured tablet with the Bayer cross on one side and FE on the other side.

PRESENTATION
Packs of 4 tablets and Packs of 100 tablets

STORAGE INSTRUCTIONS
Keep out of the reach of children. Store below 25°C.

REFERENCE NUMBER
H890 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Bayer (Pty) Ltd
27 Wrench Road
Isando
1609
Reg. No. 1968/011192/07

DATE OF PUBLICATION OF THE PACKAGE INSERT.
4 September 2008