PATIENT INFORMATION LEAFLET – YOMESAN CHEWABLE TABLETS

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

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

YOMESAN 500 mg Chewable Tablets
Niclosamide
Sugar free

Read all of this leaflet carefully before you start taking YOMESAN.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What YOMESAN is and what it is used for.
2. Before you take YOMESAN.
3. How to take YOMESAN.
4. Possible side effects.
5. How to store YOMESAN.
6. Contents of the pack and other information.

1. WHAT YOMESAN IS AND WHAT IT IS USED FOR

YOMESAN is used to treat tapeworm infections and acts directly on the head of the tapeworm (scolex). Niclosamide (the active ingredient of YOMESAN) inhibits the internal breathing of the parasite so that the head and adjoining segments die. As a result, the tapeworm loses its hold and is expelled on defecation, either whole or in smaller pieces.
YOMESAN is used in adults and children to treat the following tapeworm infections:
- Infections by beef tapeworm (*Taenia saginata*)
- Infections by pork tapeworm (*Taenia solium*)
- Infections by fish tapeworm (*Diphyllobothrium latum*)
- Infections by dwarf tapeworm (*Hymenolepis nana*)

2. BEFORE YOU TAKE YOMESAN

Do not take YOMESAN
If you are hypersensitive (allergic) to the active substance niclosamide or to any of the other ingredients of YOMESAN listed in section 6.

Other medicines and YOMESAN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
YOMESAN should not be taken together with an alcohol-containing beverage.

YOMESAN with food and drink

Acidic fruit juice such as orange juice can be very beneficial in the elimination of tapeworms.
Alcohol may increase the absorption of YOMESAN.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

There is inadequate experience of use of YOMESAN during pregnancy. If you are pregnant, you should not take YOMESAN until after giving birth. If treatment is urgently required during pregnancy, you should not take YOMESAN until the second trimester.

Breast-feeding

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 health care professional.

Driving or using machines

Because individuals react differently to YOEMSAN, you may not be able to react quickly and accurately enough to unexpected and sudden events, especially at the beginning of treatment and in conjunction with alcohol. Your ability to drive, operate machinery or work without a firm foothold may be impaired.

3. HOW TO TAKE YOMESAN

Do not share medicines prescribed for you with any other person.
Always take YOMESAN as directed in this leaflet or as your doctor, pharmacist or nurse have told you.
Check with your doctor, pharmacist or nurse if you are not sure.
The usual dose is:

Infections	**Patient group**	**Tablets (chewable) per day**	
		Day 1	**Days 2 to 7**
Beef tapeworm, Pork tapeworm, Fish tapeworm	Children aged above 6 years and adults	4 tablets (chewable)	Not applicable
	Children aged between 2 and 6 years	2 tablets (chewable)	Not applicable
	Children aged below 2 years	1 tablet (chewable)	Not applicable
Dwarf tapeworm	Children aged above 6 years and adults	4 tablets (chewable)	2 tablets (chewable) per day
	Children aged between 2 and 6 years	2 tablets (chewable)	1 tablet (chewable) per day
	Children aged below 2 years	1 tablet (chewable)	1/2 tablet (chewable) per day

YOMESAN Chewable tablets are for oral use. Take the relevant daily dose after breakfast. The tablets have a pleasant taste and should be **chewed** thoroughly and then the completely **chewed** tablet should washed down with a little water. You may also crumble the chewable tablets in water before taking them.

For young children, grind up the chewable tablets and mix them with a little water before giving them to the child to swallow.

Note
Acidic fruit juice such as orange juice can be very beneficial in the elimination of tapeworms.

In the event of constipation, regular bowel movements should be restored before treatment with YOMESAN. No special diet is necessary.
To eliminate the tapeworm rapidly and preferably in one piece after treatment, strong saline purgatives such as Glauber salts or Epsom salts should be given at the earliest two hours after the tablets (after the last dose for dwarf tapeworms). This will produce diarrhoea which will flush out the parasites.
If a purgative is not used, separate parts of the tapeworm will appear in the stool over the next few days.
Use of a strong saline purging as recommended above is essential in the case of pork tapeworm infections.

Duration of treatment

Unless otherwise prescribed, treatment for beef, pork and fish tapeworms takes one day. Treatment for dwarf tapeworms takes 7 days.
Do not take YOMESAN longer than the planned treatment duration without consulting your doctor.

Please consult your doctor or pharmacist if you have the impression that the effects of YOMESAN are too strong or too weak.

If you take more YOMESAN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
No cases of overdose have been reported.

If you forget to take YOMESAN
During treatment of the dwarf tapeworm, do not take a double dose; simply continue with the medication until the planned total dose has been taken.

If you stop taking YOMESAN

If you want to discontinue the 7-day course of treatment for dwarf tapeworm, the parasite will probably not have been killed completely and the treatment will not work. If you nevertheless insist on stopping treatment, you should in any event first consult your doctor or pharmacist.

Consult your doctor or pharmacist if you have any further questions regarding the use of this medicine.

4. POSSIBLE SIDE EFFECTS

YOMESAN can cause side effects.
Not all side effects reported for YOMESAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking YOMESAN, please consult your health care provider for advice.
It has been reported for YOMESAN that the following side effects can occur(frequencies are unknown):

- allergic reaction (e.g., with redness of the skin, severe itching and skin rash)
- anaphylactic reaction (allergic reaction - severe allergy; specific hypersensitivity reaction - which can result in life-threatening shock)
- anaphylactic shock (sudden life-threatening allergic reaction with sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing)
- dizziness (lightheadedness)
- cyanosis (blue lips)
- nausea
- vomiting
- gastrointestinal and abdominal pains (stomach ache and pain)
- retching (unproductive effort to vomit)
- diarrhoea
- rash
- pruritus (severe itching)
- hyperhidrosis (excessive sweating)
- feeling unwell (tiredness)

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: http://www.sahpra.org.za/Publicationa/index/8. By reporting side effects, you can help provide more information on the safety of YOMESAN.

5. HOW TO STORE YOMESAN

Keep out of the reach and sight of children.
Store at or below 30 °C. Do not remove from the original packaging until administered.
Return unused or expired medicines to your pharmacist for safe disposal.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What YOMESAN contains

The active ingredient is niclosamide.
The other ingredients are:
Maize starch
Talc
Sodium lauryl sulphate
Povidone
Vanillin
Magnesium stearate
Saccharin sodium

What YOMESAN looks like and contents of the packs

YOMESAN chewable tablets are grey-yellow, round tablets with FE printed on one side and the Bayer cross on the other side.

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

Holder of Certificate of Registration

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