Approved Patient Information Leaflet for Medicines for Human Use: WORMADOLE

SCHEDULING STATUS: S2

WORMADOLE, 400 mg chewable tablets

Albendazole

Contains sugar:

Each WORMADOLE 400 mg chewable tablet contains 250 mg lactose monohydrate.

Each WORMADOLE 400 mg chewable tablet contains 150 mg mannitol.

Contains sweetener:

Each WORMADOLE 400 mg chewable tablet contains 7 mg saccharin sodium.

Read all of this leaflet carefully because it contains important information for you

- WORMADOLE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use WORMADOLE carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share WORMADOLE with any other person.
- Ask your pharmacist or other health care provider if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What WORMADOLE is and what it is used for

2. What you need to know before you take WORMADOLE

3. How to take WORMADOLE

4. Possible side effects

5. How to store WORMADOLE

6. Contents of the pack and other information

Shanur Healthcare (Pty) Ltd, A38/12/0426, WORMADOLE, chewable tablets, 400 mg.

1. What WORMADOLE is and what it is used for

WORMADOLE chew tablets belong to a group of medicines known as anthelmintics, which are effective against certain worms which are parasitic in humans.

WORMADOLE is indicated in the treatment of intestinal parasites as a single oral dose.

WORMADOLE has been shown to be effective in the treatment of:

- roundworm
- whipworm
- pinworm/threadworm
- hookworm
- tapeworm.

2. What you need to know before you take WORMADOLE

Do not take WORMADOLE

- if you are hypersensitive (allergic) to albendazole or any of the other ingredients of WORMADOLE (listed in section 6).
- if you are pregnant or you are likely to become pregnant, during or shortly after the course of therapy (see "Pregnancy and Breastfeeding").

Warnings and precautions

Take special care with WORMADOLE.

- To avoid taking WORMADOLE during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test (see "Do not take WORMADOLE")
- Neurocysticercosis may manifest after a single dose of WORMADOLE. Neurocysticercosis is caused by the larval cysts of the pork tapeworm (*Taenia solium*). This is due to an inflammatory reaction in the brain, formed when the tapeworm larva/cyst is killed. This may lead to epileptic seizures, severe headaches and vision disturbances (see “Possible side effects”).

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- Leucopenia (reduction in the number of white cells in the blood) has occurred when used for periods longer than recommended.

Children

Do not give WORMSTOP to children under 1 year of age. There is limited experience with WORMADOLE in infants under 1 years of age, therefore use in this age group is not recommended.

Other medicines and WORMADOLE

Always tell your healthcare provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

Praziquantel

Praziquantel (medicines used to treat worms) as it increases the plasma levels of the albendazole active metabolite.

Ritonavir, phenytoin, carbamazepine and phenobarbital

Ritonavir (medicine used to treat human immunodeficiency virus (HIV) infection), phenytoin (medicine used to treat certain types of seizures/epilepsy), carbamazepine (medicine used to treat certain types of seizures/epilepsy) and phenobarbital (medicine used to treat certain types of seizures/epilepsy) may reduce plasma concentrations of the active metabolite of WORMADOLE; albendazole sulfoxide.

Pregnancy and, breastfeeding and fertility

WORMADOLE should not be taken by pregnant women at any stage of their pregnancy or by women who are likely to become pregnant, during or shortly after the course of therapy (see "Do not take WORMADOLE").
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking WORMADOLE.

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Driving and using machines

WORMADOLE may cause dizziness.

It is not always possible to predict to what extent WORMADOLE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which WORMADOLE affects them.

WORMADOLE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking WORMADOLE.

3. How to take WORMADOLE

Do not share medicines prescribed for you with any other person.

Always take WORMADOLE exactly as described in this leaflet or as your pharmacist or other healthcare provider have told you. Check with your pharmacist or other healthcare provider if you are not sure.

The usual dose is 400 mg WORMADOLE as a single oral dose in both adults and children over two years of age.

Duration of administration

Your doctor will tell you how long your treatment with WORMADOLE will last. If you have the impression that the effect of WORMADOLE is too strong or too weak, tell your doctor or pharmacist.

Method of administration

WORMADOLE is intended for oral use.

WORMADOLE tablets must be taken with food.

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Some people, particularly young children, may experience difficulties swallowing the tablet whole and should be encouraged to chew the tablet with a little water; alternatively, the tablet may be crushed and mixed with food.

If you take more WORMADOLE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

WORMADOLE can have side effects.

Not all side effects reported for WORMADOLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking WORMADOLE, please consult your healthcare professional for advice.

If any of the following happens, stop taking WORMADOLE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- severe skin rash, itching, fever
- neurocysticercosis (the following combination of symptoms which may occur a few hours or up to a week after taking WORMADOLE includes headache, which can be severe, nausea and vomiting, fits (seizures), problems with your vision
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)
- blistering of the skin a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

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These are all serious side effects. If you have them, you may have had a serious reaction to WORMADOLE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- headache, dizziness
- gastrointestinal discomfort (abdominal pain, nausea, vomiting), diarrhoea
- elevations of hepatic (liver) enzymes (shown in blood tests).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of WORMADOLE**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store WORMADOLE

Store all medicines out of reach of children.

Store all medicine out of reach of children. Store in a cool place (at or below 25 °C).

Store in the original package.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What WORMADOLE contains

Shanur Healthcare (Pty) Ltd, A38/12/0426, WORMADOLE, chewable tablets, 400 mg.

- The active substance is albendazole.

  Each WORMADOLE chewable tablet contains 400 mg albendazole.
- The other ingredients are sunset yellow colour, colloidal anhydrous silica, orange flavour, magnesium stearate, maize starch, lactose monohydrate, mannitol, saccharin sodium, sodium citrate.

What WORMADOLE looks like and contents of the pack

Cream or buff coloured, capsule shaped chewable tablets.

WORMADOLE is supplied in silver coloured aluminium foil strips containing 1 tablet packed into a unit carton or 500 strips packed into an outer shipper (500 tablets).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Shanur Healthcare (Pty) Ltd

Loch House Unit 003

3A Eton Road

Parktown

Johannesburg

2193

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