

Patient Information Leaflet – Approved

ALBENDAZOLE 400 COSPHARM

SCHEDULING STATUS:

S2

ALBENDAZOLE 400 COSPHARM (Chewable tablets)

Albendazole

ALBENDAZOLE 400 COSPHARM: Each tablet contains 400 mg Albendazole.

Contains sugar:

Each ALBENDAZOLE 400 COSPHARM chewable tablet contains 150 mg Lactose monohydrate.

Contains Sweetener:

Each ALBENDAZOLE 400 COSPHARM chewable tablet contains 2 mg Saccharin sodium

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

ALBENDAZOLE 400 COSPHARM is available without a doctor's prescription, for you to treat intestinal parasites. Nevertheless, you still need to use ALBENDAZOLE 400 COSPHARM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ALBENDAZOLE 400 COSPHARM with any other person.
- Ask your health care provider or pharmacist 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

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2. What you need to know before you take ALBENDAZOLE 400 COSPHARM
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1. What ALBENDAZOLE 400 COSPHARM is and what it is used for

ALBENDAZOLE 400 COSPHARM chewable tablets contains one active substance called albendazole which belongs to a group of medicines known as anthelmintics which help to treat parasites in the intestines and tissue in humans.

2. What you need to know before you take ALBENDAZOLE 400 COSPHARM

Do not take ALBENDAZOLE 400 COSPHARM:

- If you are hypersensitive (allergic) to Albendazole or any of the other ingredients of ALBENDAZOLE 400 COSPHARM tablets (listed in section 6).
- if you are pregnant or you are likely to become pregnancy, during or shortly after the course of therapy.

Warnings and precautions

Special care should be taken with ALBENDAZOLE 400 COSPHARM:

- If you are a woman of childbearing age to avoid taking ALBENDAZOLE 400 COSPHARM during early pregnancy by initiating treatment during the first week of menstruation or after a negative pregnancy test.

Treatment with a single dose of ALBENDAZOLE 400 COSPHARM may uncover a pre-existing condition known as neurocysticercosis which is caused by larval cysts of pork tapeworm in the brain. Patients may experience seizures (fits), severe headaches and vision disturbances as a result of an inflammatory reaction caused by death of the parasite in the brain after therapy with ALBENDAZOLE 400 COSPHARM.

When ALBENDAZOLE 400 COSPHARM is used for periods longer than recommended, a condition called leucopenia was noted, whereby there is a reduction in the number of white blood cells in the blood.

Children

Do not give ALBENDAZOLE 400 COSPHARM to children under 1 year as there is limited experience with ALBENDAZOLE 400 COSPHARM in this age group.

Other medicines and ALBENDAZOLE 400 COSPHARM

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

Praziquantel

Praziquantel used to treat worms, has been reported to increase the plasma levels of active albendazole metabolite.

Ritonavir, phenytoin, carbamazepine and phenobarbital

Ritonavir (medicine used to treat human immunodeficiency virus (HIV) infection), phenytoin, carbamazepine and phenobarbital (medicines used to treat certain types of seizures/epilepsy) may reduce plasma levels of active metabolite of ALBENDAZOLE 400 COSPHARM; albendazole sulfoxide. This may result in decreased efficacy of ALBENDAZOLE 400 COSPHARM.

Pregnancy, breastfeeding and fertility

ALBENDAZOLE 400 COSPHARM 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.

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.

Driving and using machines

ALBENDAZOLE 400 COSPHARM may cause dizziness.

It is not always possible to predict to what extent ALBENDAZOLE 400 COSPHARM 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 ALBENDAZOLE 400 COSPHARM affects them.

ALBENDAZOLE 400 COSPHARM contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking ALBENDAZOLE 400 COSPHARM.

3. How to take ALBENDAZOLE 400 COSPHARM

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

Always take ALBENDAZOLE 400 COSPHARM exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of ALBENDAZOLE 400 COSPHARM as a single dose in both adults and children over two years of age.

ALBENDAZOLE 400 COSPHARM tablet may be chewed or crushed and mixed with food. 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 symptoms persist after a single dose of treatment, consult your doctor or healthcare professional for further treatment. Do not exceed the maximum daily dose and treatment duration recommended.

If you take more ALBENDAZOLE 400 COSPHARM than you should

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

If you forget to take ALBENDAZOLE 400 COSPHARM

If you miss a dose of ALBENDAZOLE 400 COSPHARM, take it as soon as you remember.

Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

ALBENDAZOLE 400 COSPHARM can have side-effects.

Not all side-effects reported for ALBENDAZOLE 400 COSPHARM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALBENDAZOLE 400 COSPHARM, please consult your healthcare provider for advice.

If any of the following happens, stop taking ALBENDAZOLE 400 COSPHARM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe skin rash which may form blisters with central dark spots surrounded by paler area which look like small targets (erythema multiforme).
- Severe headaches, nausea and vomiting, seizures and problems with vision as a combination of symptoms for neurocysticercosis which may occur a few hours or up to a week after taking ALBENDAZOLE 400 COSPHARM.

- Blistering and peeling of the skin particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to ALBENDAZOLE 400 COSPHARM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Headache, dizziness,
- Abdominal pain, nausea, vomiting and diarrhoea associated with upper gastrointestinal discomfort.
- Increased liver enzymes (shown in blood tests).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ALBENDAZOLE 400 COSPHARM.

You should report suspected side effects to the Holder Of Certificate of Registration: Cospharm Investments (Pty) Ltd

The contact details for our national reporting system are:

Email: rp@cospharm.org

Tel: 010 110 9348

5. How to store ALBENDAZOLE 400 COSPHARM

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Protect from light.
- Do not use after the expiry date printed on the label.

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 ALBENDAZOLE 400 COSPHARM contains:

- The active substance is albendazole.

Each ALBENDAZOLE 400 Cospharm chewable tablet contains 400 mg albendazole.

- The other ingredients are croscarmellose sodium, lactose monohydrate, maize starch, povidone, saccharin sodium, polysorbate 80, sodium lauryl sulphate, microcrystalline cellulose, magnesium stearate, Sunset Yellow Lake and Orange Dry powder.

What ALBENDAZOLE 400 COSPHARM looks like and contents of the pack

Mottled, pale orange, rounded oblong, biconvex chewable tablets with a score line on one side and other side plain.

Albendazole 400 Cospharm is available in bulk packs of 1000s in an LDPE bag in 1800 mL HDPE jar.

Holder of Certificate of Registration

Cospharm Investments (Pty) Ltd

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Access to the corresponding Professional Information

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