

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ZENTEL 400 Tablets

Albendazole

Contains sugar (lactose): 107 mg/tablet.

Contains sweetener (sodium saccharin): 2 mg/tablet.

Read all of this leaflet carefully before you start taking ZENTEL 400.

- Keep this leaflet. You may need to read it again.
- If you have any questions, please ask your doctor, pharmacist nurse other healthcare provider.
- ZENTEL 400 has been prescribed for you personally (or your child[†]) and should not be shared with other people. It may harm them, even if their symptoms are the same as yours.

[†]Only applicable if a parent or guardian is administering the medicine.

What is in this leaflet

1. What ZENTEL 400 is and what it is used for
2. What you need to know before you take ZENTEL 400
3. How to take ZENTEL 400
4. Possible side effects
5. How to store ZENTEL 400
6. Contents of the pack and other information

1.3. SA Labelling & Packaging

1.3.2. PIL

1. What ZENTEL 400 is and what it is used for:

ZENTEL 400 is used to treat intestinal infestations caused by a variety of parasites or worms including threadworm (pinworm), roundworm, whipworm, tapeworm and hookworm. These worms and parasites usually infect the intestine but can cause problems in other parts of the body.

ZENTEL 400 works by stopping worms, parasites and their larvae from absorbing sugar (*glucose*) so that they lose energy and die. The eggs are also affected.

2. What you need to know before you take ZENTEL 400:

Do not take ZENTEL 400:

- if you are allergic (hypersensitive) to albendazole or to any of the other ingredients of ZENTEL (listed in section 6).
- if you are pregnant, if you think you could be, or if you are planning to become pregnant (refer to Pregnancy and Breastfeeding section).

If you think any of these may apply to you, **do not** take ZENTEL 400 until you have checked with your doctor.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ZENTEL 400.

You should not take ZENTEL 400 if you are pregnant, if you think you could be, or if you are planning to become pregnant or breastfeeding your baby.

ZENTEL 400 may harm unborn babies. To avoid taking ZENTEL 400 during early pregnancy, only take ZENTEL 400 during the first week of your period or after a negative pregnancy test if you are still able to become pregnant.

If you become pregnant while you are taking ZENTEL 400 see your doctor immediately.

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Driving and using machinery:

As ZENTEL 400 can cause dizziness, you should not drive a vehicle or operate machinery until you know how ZENTEL 400 affects you.

Important information about some of the ingredients of ZENTEL 400:

ZENTEL 400 contains lactose/fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ZENTEL 400. Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

ZENTEL 400 contains sunset yellow FCF (E110 or FD&C Yellow No 6) which may cause allergic-type reactions.

Taking other medicines with ZENTEL 400:

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

Some medicines may affect how ZENTEL 400 works or make it more likely that you will have side effects. These include:

- praziquantel (to treat some worm infections)
- ritonavir (to treat HIV infection)
- phenytoin, carbamazepine or phenobarbital to treat fits (*seizures*) and epilepsy.

Tell your doctor or pharmacist if you are taking any of these.

3. How to take ZENTEL 400:

The dose is one tablet once in adults and children over 2 years of age.

Swallow the tablets with water. For people, particularly young children, who may find it difficult to swallow the tablets whole, they can be chewed with a little water or crushed and mixed with food.

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It is important that you take the full course of ZENTEL 400. Do not stop unless your doctor advises you – even if you are feeling better, as your symptoms may disappear before the infection is fully cleared.

If you forget to take ZENTEL 400:

Take the dose as soon as you remember, then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much ZENTEL 400:

If you take too much ZENTEL 400 contact your doctor or pharmacist for advice.

If possible show them the ZENTEL 400 pack.

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

4. Possible side effects:

ZENTEL 400 can have side effects.

Fits (seizures) and other symptoms:

People being treated for parasite infections may also have a condition called *neurocysticercosis* meaning that they have parasites in the brain. By taking ZENTEL 400 a reaction happens in the brain when the parasites are killed. Look out for the following combination of symptoms which may occur a few hours or up to a week after taking ZENTEL 400:

- headache, which can be severe
 - nausea and vomiting
 - fits (*seizures*)
 - problems with your vision.
- ➔ Contact a doctor immediately if you get these.

Less frequent side effects:

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- headache or dizziness
 - vomiting or feeling sick, stomach pains or diarrhoea
 - skin rash
 - itchiness
 - increase in liver enzymes
 - serious skin rashes:
 - 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*)
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*).
- ➔ If you notice any of these symptoms contact a doctor urgently.

If any of these side effects get serious, please tell your doctor or pharmacist.

Not all side effects reported for ZENTEL 400 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ZENTEL 400 please consult your doctor, pharmacist or other healthcare professional for advice.

5. How to store ZENTEL 400:

Store all medicines out of reach of children.

Do not take after the expiry date shown on the pack.

Store in a cool place at or below 25 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information:

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What ZENTEL 400 contains:

ZENTEL 400 contains albendazole as the active substance. Each tablet contains 400 mg of albendazole.

The other ingredients are lactose, microcrystalline cellulose, maize starch, croscarmellose sodium, povidone, sodium lauryl sulphate, FD&C yellow no 6 aluminium lake, sodium saccharin, magnesium stearate and flavourings (orange, passion fruit and vanilla).

What ZENTEL 400 looks like and contents of the pack:

Mottled pale orange rounded oblong biconvex tablets with a score line on one side and embossed 'ALB 400' on the other side, and with a fruity smell.

ZENTEL 400 is available in blister pack strips of one tablet each packed in an outer carton or plastic securitainers containing 100 or 500 tablets.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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7460

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