ZENTEL 400

ZENTEL SUSPENSION 20 mg/ml

Albendazole

QUALITATIVE AND QUANTITATIVE COMPOSITION

ZENTEL 400:

Contains 400 mg albendazole per tablet.

*C*ontains sugar (lactose): 107 mg/tablet.

Contains sweetener (lactose): 2 mg/tablet

ZENTEL SUSPENSION 20 mg/ml:

2 % *w/v* suspension to be taken orally; 2 g albendazole per 100 ml.

Sugar-free.

Contains sweetener (saccharin sodium): 0,05 % *m/v*

PHARMACEUTICAL FORM

Tablet:

Mottled pale orange rounded oblong biconvex tablets with a score line on one side and embossed “ALB 400” on the reverse and with a characteristic fruity odour.

Suspension:

A white to cream coloured, pleasant tasting, orange-vanilla flavoured suspension.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

CLINICAL PARTICULARS

Indications

ZENTEL is a benzimidazole carbamate with anthelmintic and anti-protozoal activity against the following intestinal and tissue parasites: Roundworm (*Ascaris lumbricoides*), pinworm (*Enterobius vermicularis*), hookworm (*Necator americanus, Ancylostoma duodenale*), whip-worm (*Trichuris trichiura*), threadworm (*Strongyloides stercoralis*), tapeworm (*Taenia spp.* and *Hymenolepis nana* only in the case of associated parasitism), Chlonorchiasis (*Chlonorchis sinensis*), Opisthorchiasis (*Opisthorchis viverrini*) and cutaneous larva migrans; Giardiasis (*G.lamblia*, *G.duodenalis*, *G.intestinalis*, *Lamblia intestinalis*) in children.

Dosage and Administration

Dosage

Indications	Age	Dose	Period
- Roundworm - Pinworm* - Hookworms - Whipworm	Adults and children over 2 years of age.	400 mg [one 400 mg tablet or 20 ml 2 % suspension][#]	Single dose.
	Children 1-2 years of age.	200 mg (10 ml 2 % suspension)	Single dose.
- Strongyloidiasis - Taeniasis - Hymenolepiasis[=]	Adults and children over 2 years of age.	400 mg ([#]see above)	One dose per day for 3 days.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

- Chlonorchiasis - Opisthorchiasis	Adults and children over 2 years of age.	400 mg (#see above)	Two doses per day for 3 days.
- Cutaneous larva migrans	Adults and children over 2 years of age.	400 mg (#see above)	One dose per day for 1 to 3 days.
- Giardiasis	Children 2 – 12 years of age only.	400 mg (#see above)	One dose per day for 5 days.

*In order to obtain a complete cure in the case of pinworm infestation, prescribe strict measures of hygiene, also treat the relatives and individuals sharing the same housing.

=In cases of proven Hymenolepiasis, retreatment in 10 to 21 days is recommended.

Method of Administration

If the patient is not cured after three weeks, a second course of treatment is indicated.

No special procedures, such as fasting or purging, are required.

The tablets can be chewed or taken with water. Some people, particularly young children, may experience difficulties swallowing the tablets whole and should be encouraged to chew the tablets with a little water, alternatively the tablets may be crushed.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Special Patient Populations

- **Elderly**

Experience in patients 65 years of age or older is limited. Reports indicate that no dosage adjustment is required, however, *ZENTEL* should be used with caution in elderly patients with evidence of hepatic dysfunction (see *Hepatic Impairment* and *Pharmacokinetics*).

- **Renal impairment**

Since renal elimination of albendazole and its primary metabolite, albendazole sulfoxide, is negligible, it is unlikely that clearance of these compounds would be altered in these patients. No dosage adjustment is required, however, patients with evidence of renal impairment should be carefully monitored.

- **Hepatic impairment**

Since albendazole is rapidly metabolised by the liver to the primary pharmacologically active metabolite, albendazole sulfoxide, hepatic impairment would be expected to have significant effects on the pharmacokinetics of albendazole sulfoxide. Patients with abnormal liver function test results (transaminases) prior to commencing albendazole therapy should be carefully monitored.

Contraindications

ZENTEL should not be administered during pregnancy, or in women thought to be pregnant.

ZENTEL is contraindicated in patients with a known history of hypersensitivity to the drug (albendazole or constituents).

Warnings and Precautions

In order to avoid administering *ZENTEL* during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Treatment with *ZENTEL* may uncover pre-existing neurocysticercosis, particularly in areas with high taenosis infection. Patients may experience neurological symptoms e.g. seizures, increased intracranial pressure and focal signs as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.

ZENTEL 400 tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

ZENTEL SUSPENSION 20 mg/ml contains benzoic acid which is a mild irritant to the skin, eyes and mucous membrane. It may increase the risk of jaundice in newborn babies.

Interactions

Praziquantel has been reported to increase the plasma levels of the albendazole active metabolite.

Ritonavir, phenytoin, carbamazepine and phenobarbital may have the potential to reduce plasma concentrations of the active metabolite of albendazole; albendazole sulfoxide. The clinical relevance of this is unknown, but may result in decreased efficacy, especially in the treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies.

Pregnancy and Lactation

Pregnancy

ZENTEL should not be administered during pregnancy or in women thought to be pregnant (see *Contraindications*).

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Lactation

It is not known whether albendazole or its metabolites are secreted in human breast milk. Thus *ZENTEL* should not be used during lactation unless the potential benefits are considered to outweigh the potential risks associated with treatment.

Effects on Ability to Drive and Use Machines

There have been no studies to investigate the effect of ZENTEL on driving performance or the ability to operate machinery. However, when driving vehicles or operating machinery, it should be taken into account that dizziness has been reported after using ZENTEL (see Adverse Reactions).

Adverse Reactions

Data from large clinical studies were used to determine the frequency of very common to rare undesirable reactions. The frequencies assigned to all other undesirable reactions (i.e. those occurring at < 1/1000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

The following convention has been used for the classification of frequency:

Very common	≥1/10
Common	≥1/100 to <1/10
Uncommon	≥ 1/1000 to < 1/100
Rare	≥ 1/10,000 to < 1/1000
Very rare	< 1/10,000

Immune system disorders

Rare: Hypersensitivity reactions including rash, pruritus and urticaria.

Nervous system disorders

Uncommon: Headache and dizziness.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Gastrointestinal disorders

Uncommon: Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea.

Hepatobiliary disorders

Rare: Elevations of hepatic enzymes

Skin and subcutaneous tissue disorders

Very rare: Erythema multiforme, Stevens-Johnson syndrome

Overdose

Treatment

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

ATC code

P02CA03

Mechanism of Action

Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and it is thought to exert its anthelmintic effect by inhibiting tubulin polymerisation. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Pharmacokinetics

Absorption

In man, albendazole is poorly absorbed (less than 5 %) following oral administration.

The systemic pharmacological effect of albendazole is augmented if the dose is administered with a fatty meal, which enhances the absorption by approximately five-fold.

Distribution

Following oral administration of a single dose of 400 mg albendazole, the pharmacologically active metabolite, albendazole sulfoxide, has been reported to achieve plasma concentrations from 1.6 to 6.0 micromol/L when taken with breakfast.

Metabolism

Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma. Albendazole sulfoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections.

Elimination

The plasma half-life of albendazole sulfoxide is 8.5 hours.

Albendazole sulfoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine.

Special Patient Populations

- **Elderly**

Although no studies have investigated the effect of age on albendazole sulfoxide

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

pharmacokinetics, data in 26 hydatid cyst patients (up to 79 years) suggest pharmacokinetics similar to those in young healthy subjects. The number of elderly patients treated for either hydatid disease or neurocysticercosis is limited, but no problems associated with an older population have been observed.

- **Renal Impairment**

The pharmacokinetics of albendazole in patients with impaired renal function have not been studied.

- **Hepatic Impairment**

The pharmacokinetics of albendazole in patients with impaired hepatic function have not been studied.

PHARMACEUTICAL PARTICULARS

List of Excipients

Tablet 400 mg	**Suspension (2 %)**
Lactose	Aluminium magnesium silicate
Microcrystalline cellulose	Carboxymethylcellulose sodium
Maize starch	Glycerin
Croscarmellose sodium	Polysorbate 80
Povidone K30	Sorbitan monolaureate
Sodium lauryl sulphate	Potassium sorbate
Sunset yellow lake	Benzoic acid (see *Warnings and Precautions*)
Sodium saccharin	Sorbic acid
Magnesium stearate*	Silicone antifoam 1510

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Flavourings (orange, passion fruit and vanilla)	Saccharin sodium
	Flavourings (orange, passion fruit and vanilla)

* Magnesium Stearate is of vegetable origin.

Shelf-Life

The expiry date is indicated on the packaging.

Special Precautions for Storage

Keep out of reach of children.

Tablet:

Store below 30 °C. The shelf-life depends on the locally registered storage conditions (refer to the pack for information).

Suspension:

Store at or below 25 °C and protect from direct sunlight.

Nature and Contents of Container

Tablet:

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

Suspension:

ZENTEL SUSPENSION 20 mg/ml is available in a 20 ml white coloured PVC bottle fitted with a red pilfer proof screw aluminium cap.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Not all presentations are available in every country.

Instructions for Use/Handling

Suspension: Shake well before use.

Name and address of the holder of the certificate of registration

GlaxoSmithKline South Africa (Pty) Ltd

57 Sloane Street

Bryanston, 2021

South Africa

Manufacturer

Tablet:

GlaxoSmithKline Consumer Healthcare S.A. (Pty) Ltd, 39 Hawkins Avenue,
Epping Industria 1, 7460

Suspension:

Farmaclair, 440 Avenue du Général de Gaulle, 14200 Hérouville, Saint Clair, France

Registration details

Tablet:

Botswana: Reg No BOT1101811 (A/B) S2

Malawi: Reg No PMPB/PL270/150 P

Namibia: Reg No 10/12/0373 NS2

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Zambia: Reg No 179/022 POM

Zimbabwe: Reg No 2014/7.7/4838 P

Suspension:

Botswana: Reg No BOT9900418 S2

Malawi: Reg No PMPB/PL270/63 P

Namibia: Reg No 90/12/001614 NS2

Zambia: Reg No 179/033 POM

Zimbabwe: Reg No 83/7.7/1656 P

Version number: GDS26/IPI10

Date of issue: 08 Dec 2017

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

PATIENT LEAFLET

ZENTEL 400

ZENTEL SUSPENSION 20 mg/ml

Albendazole

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

In this leaflet:

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 "Contains sweetener (sodium saccharin): 2 mg/tablet" (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: "Store at or below 25 °C" for tablets to "Store below 30 °C" – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: "Do not store ZENTEL above 25 °C." to "Do not store ZENTEL above 30°C"

1. What ZENTEL is and what it is used for

ZENTEL contains a medicine called albendazole. It belongs to a group of medicines called anthelmintics and is used to treat infections 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 works by stopping worms, parasites and their larvae from absorbing sugar (*glucose*) so that they lose energy and die.

2. Before you take ZENTEL

Don't take ZENTEL

- if you are **pregnant,** if you **think you could be,** or if you are **planning to become pregnant** (see *Pregnancy and breast-feeding* in Section 2).
- if you are **allergic** (hypersensitive) to albendazole or any other ingredients of ZENTEL (listed in 'what ZENTEL contains' within Section 6)

➔ If you think any of these may apply to you, **don't take ZENTEL** until you have checked with your doctor.

Take special care with ZENTEL 400 and ZENTEL SUPSENSION

Before you/your child take ZENTEL your doctor needs to know:

• if your child is **under 6 years old**

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 "Contains sweetener (sodium saccharin): 2 mg/tablet" (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: "Store at or below 25 °C" for tablets to "Store below 30 °C" – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: "Do not store ZENTEL above 25 °C." to "Do not store ZENTEL above 30°C"

- if you/your child have **liver disease**
- if you/your child have **kidney disease.**

Take special care with ZENTEL 400:
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take this medicinal product.

Take special care with ZENTEL SUSPENSION:
If there is any contact with the skin and/or eyes wash the affected area immediately as ZENTEL SUSPENSION contains benzoic acid which can irritate skin and eyes.

Women of childbearing age

To avoid taking ZENTEL during early pregnancy, see Pregnancy and breast-feeding in Section 2.

Conditions you need to look out for

People being treated for parasite infections can also have a rare and serious brain infection called *neurocysticercosis* but they don't always know that they have it. This may cause fits (seizures) and other symptoms, see 'Conditions you need to look out for' in Section 4.

Blood tests and ZENTEL

ZENTEL can:

- reduce the number of blood cells produced in the body
- increase the levels of enzymes (chemicals found in the blood) that are produced by the liver.

Depending on the results you may have to stop treatment permanently or for a short time. Your doctor may take blood samples to check the number of blood cells and your liver enzymes before and during treatment.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 "Contains sweetener (sodium saccharin): 2 mg/tablet" (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: "Store at or below 25 °C" for tablets to "Store below 30 °C" – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: "Do not store ZENTEL above 25 °C." to "Do not store ZENTEL above 30°C"

Other medicines and ZENTEL

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

- cimetidine (to treat **stomach ulcers**)
- praziquantel (to treat some **worm infections**)
- dexamethasone (to treat **inflammation or allergy**)
- 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. Your doctor may decide you need further check-ups or may adjust your dose accordingly.

Pregnancy and breast-feeding

ZENTEL may harm unborn babies. **Don't take ZENTEL** if you are **pregnant**, if you **think you could be,** or if you are **planning to become pregnant**.

- **Tell your doctor if you are pregnant** or planning to become pregnant.
- **Use a reliable method of contraception** while you're taking ZENTEL to prevent pregnancy.
- **If you do become pregnant during treatment** with ZENTEL, tell your doctor.

It is not known whether the ingredients of ZENTEL can pass into breast milk. **If you are breast-feeding, you must check with your doctor** before you take ZENTEL.

Driving and using machines

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

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 "Contains sweetener (sodium saccharin): 2 mg/tablet" (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: "Store at or below 25 °C" for tablets to "Store below 30 °C" – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: "Do not store ZENTEL above 25 °C." to "Do not store ZENTEL above 30°C"

Important information about some of the ingredients of ZENTEL

ZENTEL 400 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

ZENTEL SUSPENSION 20 mg/ml contains benzoic acid which is a mild irritant to the skin, eyes and mucous membrane. It may increase the risk of jaundice in newborn babies.

3. How to take ZENTEL

How much to take

Always take ZENTEL exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

Your doctor will decide on the correct dose of **ZENTEL** and for how long you (or your child) need to take it. This will depend on your weight, age and the type and severity of your infection.

How to take ZENTEL

It is best to take ZENTEL at the same time each day.

You can take ZENTEL with or without food.

Tell your doctor if you continue to experience symptoms of your illness, 3 weeks after starting treatment with ZENTEL.

Tablets

Swallow the tablets with water. For people, particularly young children, who may find it difficult to swallow the tablets whole, crush or chew the tablet and take with a little water.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Suspension

Shake the suspension well before use.

If you forget to take ZENTEL

Take the dose as soon as you remember, then take your next dose at the usual time. **Don't 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

If you take too much ZENTEL, **contact your doctor or pharmacist for advice.** If possible, show them the ZENTEL pack.

Don’t stop ZENTEL without advice

It is important that you take the full course of ZENTEL. Don’t stop unless your doctor advises you to – even if you are feeling better. If you don't complete the full course of treatment, the infection may come back.

4. Possible side effects

Like all medicines, ZENTEL can cause side effects, but not everybody gets them.

Serious skin reactions: get a doctor’s help straight away

A small number of people taking ZENTEL get an allergic reaction which may develop into more serious, and even life-threatening, problems if they are not treated. Symptoms of these reactions include:

- 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)*
- widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals *(Stevens–Johnson syndrome).*

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

➔ **If you notice any of these symptoms contact a doctor urgently**.

Conditions you need to look out for

Fits (*seizures*) and other symptoms

People being treated for parasite infections may also have a rare and serious condition called *neurocysticercosis* meaning that they have parasites in the brain. By taking ZENTEL a reaction happens in the brain when the parasites are killed. Look out for the following combination of symptoms:

- headache, which can be severe
- feeling sick (*nausea*) and vomiting
- fits (*seizures*)
- problems with your vision.

➔ **Contact a doctor immediately** if you get these.

Uncommon side effects

These may affect **up to 1 in 100** people:

- headache
- dizziness
- feeling sick (nausea)
- vomiting
- stomach pains
- diarrhoea

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Rare side effects

These may affect **up to 1 in 1,000** people:

- allergic reaction including skin rash and itchiness
- yellowing of skin or eyes
- increase in chemicals (enzymes) from the liver

Very rare side effects

These may affect **up to 1 in 10,000** people:

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)*
- 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**. (See 'Serious skin reactions' earlier in Section 4)

If you get side effects

Tell your doctor or pharmacist if any of the side effects becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 "Contains sweetener (sodium saccharin): 2 mg/tablet" (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: "Store at or below 25 °C" for tablets to "Store below 30 °C" – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: "Do not store ZENTEL above 25 °C." to "Do not store ZENTEL above 30°C"

5. How to store ZENTEL

Keep out of the reach and sight of children.

Do not use ZENTEL after the expiry date shown on the pack.

Tablets

Do not store ZENTEL above 30 °C.

Suspension

Do not store ZENTEL above 25 °C. Protect from direct sunlight.

If you have any unwanted ZENTEL tablets or suspension, don't put into waste water or household rubbish. Ask your pharmacist how to dispose of tablets or suspension that you don't need. This will help to protect the environment.

6. Further information

What ZENTEL contains

The active substance is albendazole.

Tablet

Each tablet contains 400 mg albendazole.

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 "Contains sweetener (sodium saccharin): 2 mg/tablet" (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: "Store at or below 25 °C" for tablets to "Store below 30 °C" – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: "Do not store ZENTEL above 25 °C." to "Do not store ZENTEL above 30°C"

The other ingredients are:

Lactose, microcrystalline cellulose, maize starch, croscarmellose sodium, povidone K30, sodium lauryl sulphate, sunset yellow lake, sodium saccharin, magnesium stearate*, flavourings (orange, passion fruit and vanilla).

* Magnesium Stearate is of vegetable origin.

ZENTEL 400 contains sugar (lactose): 107 mg/tablet.
ZENTEL 400 contains sweetener (sodium saccharin): 2 mg/ tablet

Suspension

Each ml of suspension contains 20 mg albendazole (400 mg/20 ml)

The other ingredients are:

Aluminium magnesium silicate, carboxymethylcellulose sodium, glycerin, polysorbate 80, sorbitan monolaureate, potassium sorbate, benzoic acid, sorbic acid, silicone antifoam 1510, saccharin sodium, flavourings (orange, passion fruit and vanilla).

ZENTEL SUSPENSION 20 mg/ml is sugar-free.
Contains sweetener (saccharin sodium): 0,05 % *m/v.*

What ZENTEL looks like and contents of the pack

Tablet

Mottled pale orange rounded oblong biconvex tablets with a score line on one side and embossed “ALB 400” on the reverse and with a characteristic fruity odour.
ZENTEL 400 tablets are available in blister pack strips of one tablet each packed in an outer carton or plastic securitainers containing 100 or 500 tablets.

Suspension

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

A white to cream coloured, pleasant tasting, orange-vanilla flavoured suspension.

ZENTEL SUSPENSION 20 mg/ml is available in a 20 ml white coloured PVC bottle fitted with a red pilfer proof screw aluminium cap.

Not all presentations are available in every country.

Name and address of the holder of the certificate of registration

GlaxoSmithKline South Africa (Pty) Ltd
57 Sloane Street
Bryanston, 2021
South Africa

Registration details

Tablet

Botswana: Reg No BOT1101811 (A/B) S2

Malawi: Reg No PMPB/PL270/150 P

Namibia: Reg No 10/12/0373 NS2

Zambia: Reg No 179/022 POM

Zimbabwe: Reg No 2014/7.7/4838 P

Suspension

Botswana: Reg No BOT9900418 S2

Malawi: Reg No PMPB/PL270/63 P

Namibia: Reg No 90/12/001614 NS2

Zambia: Reg No 179/033 POM

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”

Zimbabwe: Reg No 83/7.7/1656 P

Version number: GDS26/IPI10

Date of issue: 08 Dec 2017

Notes:

1. Added to PI & PIL for tablets on 2019.09.18 “Contains sweetener (sodium saccharin): 2 mg/tablet” (As per the submitted Rebaseline dossier) – To be included in next update.
2. Changed in PI for tablets on 2019.09.18: “Store at or below 25 °C” for tablets to “Store below 30 °C” – To be included in next update
3. Changed in PIL for tablets on 2019.09.18: “Do not store ZENTEL above 25 °C.” to “Do not store ZENTEL above 30°C”