
PATIENT INFORMATION LEAFLET

HELMADOL 400 mg Film Coated Tablets

For oral use.

Each film tablet contains;

Active substance: 400 mg Albendazole

Excipients: Lactose monohydrate, Maize starch pregelatinized, Sodium starch glycolate, Crospovidone, Polyvinyl pyrrolidone K25, Sodium lauryl sulphate, Talc, Magnesium stearate, Polyvinyl alcohol, Polyethylene glycol, Titanium dioxide (E171) and Red iron oxide (E172), Purified water.

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 further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *If you go to doctor or hospital at the time of using this medicine, please tell your doctor.*
- *Please follow the instructions exactly. Do not use another **high or low doses** out of recommended.*

In this leaflet:

- 1. What HELMADOL is and what it is used for***
- 2. Before you take HELMADOL***
- 3. How to take HELMADOL***
- 4. What are possible side effects?***
- 5. How to store HELMADOL***

1. What HELMADOL is and what it is used for

HELMADOL contains 400 mg albendazole and is presented as 2 film coated tablets in blister. Film coated tablets are pink colored, oval with a notch on one side and biconvex. HELMADOL is an anthelmintic medicine. HELMADOL prevents newly hatched insect larval from growing or multiplying in body. Albendazole is used to treat certain infections caused by worms such as pork tapeworm and dog tapeworm.

Albendazole may also be used for purposes not listed in this leaflet.

2. Before you take HELMADOL

Do not take HELMADOL in following conditions:

If you are sensitive (allergic) to similar drugs such as albendazole or mebendazole.

Take special care with HELMADOL in following conditions:

- If you have liver problems or if you ever have ever had abnormal liver function tests,
- HELMADOL can lower the blood cells that help your body fight infections. This can make it easier for you to bleed from an injury or get sick from being around others who are ill. If your blood cell levels are too low, take HELMADOL with special care.

If these remarks are true for you at any time even if in the past, please consult your doctor.

Taking HELMADOL with food and drink

Take HELMADOL with meals to reduce your nausea.

Pregnancy

Ask your doctor or pharmacist for advice before taking medicine.

Do not take HELMADOL if you are pregnant or planning to be pregnant. Women should avoid becoming pregnant while taking HELMADOL and after 1 month by using suitable contraception.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Ask your doctor or pharmacist for advice before taking medicine.

It is not known whether HELMADOL excretes in breast milk. However, breastfeeding mothers should be careful, since a lot of medicine may excrete in breast milk.

Driving and using machines

Any effect on driving and using machines is not reported.

Important information about some of the ingredients of HELMADOL

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars; contact your doctor before taking this medicinal product.

HELMADOL contains less than 1 mmol (23 mg) sodium in its each dose. There is no side effects expected related to this dosage of sodium.

Taking other medicines

Taking HELMADOL with following medicines may be undesirable;

- Cimetidine,
- Dexamethasone,
- Praziquantel,
- Theophylline.

There may be other medicines interact with HELMADOL. Do not take new medicine without asking your doctor including vitamins, minerals, and herbal products.

Ask your doctor or pharmacist for advice before taking any medicine if you are taking any other medicine with or without prescription.

3. How to Take HELMADOL

Always take this medicine as your doctor has told you. General dosage is presented below;

Posology/ frequency and time of administration

Cystic hydatid disease:

In patients weigh 60 kg or greater:

400 mg is taken twice daily, with meals for 28 days. This 28-day treatment period may be repeated after a 14-day period without treatment for a total of 3 cycles.

In patients weigh less than 60 kg:

15 mg/kg is taken twice daily, with meals for 28 days. This 28-day treatment period may be repeated after a 14-day period without treatment for a total of 3 cycles.

Neurocysticercosis:

In patients weigh 60 kg or greater:

400 mg is taken twice daily, with meals for 8 to 30 days.

In patients weigh less than 60 kg:

15 mg/kg is taken twice daily, with meals for 8 to 30 days.

Other Helminthiasis Infections:

Dosage scheme for adults:

Ascariasis, Enterobiasis (Oxyuriasis), hookworm disease (*N.americanus, A.duodenale*),

Trichuriasis, Trichostrongyliasis: Single dosage of 400 mg albendazole (1 x HELMADOL 400 mg Film Coated Tablets) should be taken in one go. Treatment may be repeated after 3 weeks.

Taeniasis (*T.saginata, T.solium*) and Strongyloidiasis: 400 mg albendazole (1 x HELMADOL 400 mg Film Coated Tablets) should be taken once daily for 3 days consecutively. Treatment may be repeated after 3 weeks.

Capillariasis: 200 mg albendazole (1/2 x HELMADOL 400 mg Film Coated Tablets) should be taken 2 times daily for 10 days.

Trichinosis: 400 mg albendazole (1 x HELMADOL 400 mg Film Coated Tablets) should be taken 2 times daily for 15 days.

Chlonorchiasis: 400 mg albendazole (1 x HELMADOL 400 mg Film Coated Tablets) should be taken 1 or 2 times daily for 7 days or 10 mg/kg albendazole should be taken 2 times daily for 7 days.

Giardiasis: 400 mg albendazole (1 x HELMADOL 400 mg Film Coated Tablets) should be taken daily for 3 days.

Method of administration:

HELMADOL is for oral use only.

Tablets should be taken at least with a glass of water (approximately 120 ml) on a full stomach. Some people, particularly children, may experience difficulties swallowing the tablets whole. In these situations, tablets should be crushed or chewed and swallowed with a drink of water.

Different age groups:

Use in children:

Experience in children under the age of 6 is limited.

Dose scheme for adults is applied in neurocysticercosis and cystic hydatid disease.

Ascariasis, Enterobiasis (Oxyuriasis), hookworm disease (*N.americanus*, *A.duodenale*),

In Trichuriasis treatment:

- In children up to 2 years: single dosage of 200 mg albendazole (1/2 x HELMADOL 400 mg Film Coated Tablets) only once. Treatment may be repeated after 3 weeks.
- In children older than 2 years: Dosage diagram for adults is applied.

In Taeniasis ve Strongyloidiasis treatment:

- In children up to 2 years: 200 mg albendazole (1/2 x HELMADOL 400 mg Film Coated Tablets) should be taken once daily for 3 days consecutively. Treatment may be repeated after 3 weeks.
- In children older than 2 years: Dosage diagram for adults is applied.

In Capillariasis treatment: 200 mg albendazole (1/2 x HELMADOL 400 mg Film Coated Tablets) two times daily.

In Trichostrongyliasis treatment: Single dosage of 400 mg albendazole (1 x HELMADOL 400 mg Film Coated Tablets).

Use in elders:

Same dose with adults can be applied.

Special use conditions:

Renal Failure:

Inform your doctor for dose adjustment if you have renal failure.

Hepatic impairment

Inform your doctor for dose adjustment if you have hepatic impairment.

If you have an impression about that effect of HELMADOL is too strong or too weak, consult your doctor or pharmacist.

If you take more HELMADOL than you should;

If you use more HELMADOL than you should, talk to a doctor or pharmacist.

Supportive treatment and treatment against symptoms are applied.

If you forget to take HELMADOL;

If you forget to take your medicine, do not worry, take your medicine as soon as possible when you notice. If your next scheduled dose is very close, wait until then and continue taking your tablets as usual.

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

Effects that may occur when treatment with HELMADOL is terminated;

Take your medicine until the treatment period that recommended by your doctor completes. Your symptoms may get better before you are fully recovered, in this case do not terminate treatment.

4. What are possible side effects?

Like all medicines, side effects may occur in patients with hypersensitivity to ingredients containing in HELMADOL.

If you have any of the following symptoms, stop taking HELMADOL and tell your doctor IMMEDIATELY or go to an emergency department of the closest hospital:

- Urticaria (a skin disease generally with itchiness),
- Difficulty in breathing,
- Swelling in face, lips, tongue and throat.

These are all very serious side effects. If you have one of them that means you have a severe allergy to HELMADOL. You may need emergency medical intervention or to be hospitalized. All of these very serious side effects are seen very rarely.

If you notice any of the following symptoms, tell your doctor immediately or go to an emergency department of the closest hospital:

- Easy bruising or bleeding, excessive weakness,
- Fever, sore throat, severe headache, skin exfoliation and red skin rash,
- Fever with chills, pain in body and flu symptoms.

These are serious side effects. Emergency medical intervention may be needed. Serious side effects are seen very rarely.

If you notice any of the following symptoms, tell your doctor:

- Abdominal pain,
- Nausea, vomiting,
- Headache, dizziness,
- Temporal alopecia.

These are mild side effects of HELMADOL. Frequencies of these side effects are unknown, cannot be estimated from available data.

If you experience any side effects that are not stated in this patient information leaflet, inform your doctor or pharmacist.

5. How to Store HELMADOL

Keep this medicine out of the sight and reach of children in its original package.

Store at room temperature below 30°C.

Use in accordance with the expiry date.

Do not use HELMADOL after expiry date on its package.

Do not use HELMADOL if you notice any defects in product and/or package.

Marketing Authorization Holder

World Medicine Ilac Sanayi ve Tic. A.Ş.
Bağcılar, İstanbul/TURKEY

Manufacturer

World Medicine Ilac Sanayi ve Tic. A.Ş.
15 Temmuz Mahallesi, Cami Yolu Caddesi No:50 Güneşli / Bağcılar / İstanbul / TURKEY