

## **Package leaflet: Information for the patient**

### **BLISZOLE 400 Tablets**

Albendazole Tablets 400 mg

Please read this leaflet carefully before using this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

#### **In this leaflet:**

- **1. What BLISZOLE 400 Tablets is and what it is used for?**
- **2. Before you take BLISZOLE 400 Tablets**
- **3. How to take BLISZOLE 400 Tablets?**
- **4. Possible side effects**
- **5. How to store BLISZOLE 400 Tablets?**
- **6. Further information**

#### **1. What BLISZOLE 400 Tablets is and what it is used for?**

BLISZOLE 400 is a benzimidazole carbamate with anthelmintic and Antiprotozoal activity against the intestinal and tissue worm infections.

BLISZOLE 400 is used for the treatment of common worm infections of the gut, as such as the following conditions caused by sensitive intestinal helminths/protozoa:

- Pinworm infection (enterobiasis)
- Hookworm disease (ancylostomiasis and necatoriasis)
- Dwarf tapeworm infection (hymenolepsiasis)
- Pork/beef tapeworm infections (taeniasis)
- Threadworm infection (strongyloidiasis)
- Roundworm infection (ascariasis)
- Whipworm infection (trichuriasis)
- Liver fluke infections (clonorchiasis and opisthorchiasis)
- Hookworm (animal origin) causing skin disease (cutaneous larva migrans)
- Giardia infection (giardiasis in children)

#### **2. Before you take BLISZOLE 400 Tablets**

Do not take BLISZOLE 400 tablets if you are allergic to albendazole or any other anthelmintic or to any of the ingredients listed in section 6 of this leaflet.

## **TAKE SPECIAL CARE WITH BLISZOLE 400**

If you have eye problems (especially a problem with your retina), liver disease, or bone marrow suppression.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines especially Dexamethasone, Praziquantel, Cimetidine etc. Other drugs may affect albendazole, including prescription and over-the-counter medicines, vitamins, and herbal products. This is because BLISZOLE 400 can affect the way some other medicines work. Also, some other medicines can affect the way BLISZOLE 400 works.

### **Taking BLISZOLE 400 with food and drink:**

You should take each dose of BLISZOLE 400 with a meal. Taking it on an empty stomach may lead to inadequate blood levels and reduced effectiveness of the medication. Grapefruit juice can also increase the absorption of albendazole.

## **PREGNANCY AND BREAST FEEDING**

BLISZOLE 400 should not be used during pregnancy or in women who think they may be pregnant. It is advised that women of childbearing age take effective contraceptive precautions during treatment and for one month after completion of it.

It is convenient to rule out pregnancy in women of childbearing age before starting treatment, by using a pregnancy test. It is also advisable to start treatment during the first consecutive week at the start of menstruation.

This medicine may increase the risk of jaundice in new born babies.

## **DRIVING AND USING MACHINES**

There are no data to suggest that albendazole may affect the ability to drive or operate machinery. The effect of alcohol may potentiate sedation and this may affect the ability to drive or operate machinery.

Consult your doctor or pharmacist before taking any medicine.

### **3. How to take BLISZOLE 400 Tablets?**

- For hydatid disease of the liver, lung, and peritoneum:
- **Adults** weighing 60 kilograms (kg) or more —Dose is based on body weight and must be determined by your doctor. The dose is usually 400 milligrams (mg) 2 times a day, taken with meals for 28 days (1 cycle). This is followed by not taking BLISZOLE 400 for 14 days, for a total of 3 cycles.

- **Children**—Use and dose must be determined by your doctor.
- Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.
- Take BLISZOLE 400 until you finish the prescription, even if you feel better. If you stop taking BLISZOLE 400 too soon or skip doses, your infection may not be completely treated.

#### **4. Possible side effects**

Possible side effects of BLISZOLE 400 tablet is sore throat, mouth sores, feeling light headed, seizure; or increased pressure inside the skull-severe headaches, ringing in your ears, dizziness, nausea, vomiting vision problems, pain behind your eyes, neck stiffness, increased sensitivity to light, confusion ,fever, stomach pain, abnormal ,liver function tests, spinning sensation, or temporary hair loss. Itching, tired feeling, loss of appetite, dark urine, jaundice (yellowing of the skin or eyes).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

#### **5. How to store BLISZOLE 400 Tablets?**

- Keep BLISZOLE 400 and all the medicines out of reach and sight of children.
- Store BLISZOLE 400 tablets at room temperature, 68°F to 77°F (20°C to 25°C).
- Throw away BLISZOLE 400 that is no longer needed or expired (out of date).
- Keep BLISZOLE 400 in the container that it came in and keep the container tightly closed.
- Do not use BLISZOLE 400 if the original seal over the container opening is broken or missing.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

## **6. Further information**

### **What BLISZOLE 400 Tablet contains:**

#### **Active substance:**

Each uncoated chewable tablet contains: Albendazole 400 mg.

#### **Other ingredients:**

Maize Starch, Sucrose, Lactose, Sodium Saccharine, Sodium Lauryl Phosphate, Sodium Benzoate, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate, Purified Water, P.V.K.P-30

### **What BLISZOLE 400 tablet looks like and contents of the pack:**

An Orange coloured, capsule shaped uncoated tablet having 400 engraved on one side and break line on another side supplied in carton of 25 x 1 Tablets.

### **Supplier and Manufacturer**

#### **CENTURION REMEDIES PVT. LTD.**

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### **Local Representative's Name & Address**

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