



บริษัท ยูนิชั่น จำกัด
UNISON LABORATORIES CO., LTD.



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PART-I

Section E.8

Proposed Patient Information Leaflet



Cert. No. TH03/0195



Cert. No. NQ366/01



Unison Laboratories Co., Ltd.

PACKAGING MATERIALS

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MESIN-C 200 mg/ 5 mL Oral Suspension

Each teaspoonful (5 mL) of suspension contains:
Albendazole 200 mg

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❖ What is MESIN-C 200 mg/ 5 mL Oral Suspension?

MESIN-C 200 mg/ 5 mL Oral Suspension is a vermicide; Active ingredient is Albendazole, which causes degenerative alterations in the tegument and intestinal cells of the worm by binding to the colchicine-sensitive site of tubulin, thus inhibiting its polymerization or assembly into microtubules. The loss of the cytoplasmic microtubules leads to impaired uptake of glucose by the larval and adult stages of the susceptible parasites, and depletes their glycogen stores. Degenerative changes in the endoplasmic reticulum, the mitochondria of the germinal layer, and the subsequent release of lysosomes result in decreased production of adenosine triphosphate (ATP), which is the energy required for the survival helminth. Due to diminished energy production, the parasite is immobilized and eventually dies.

Albendazole also has been shown to inhibit the enzyme fumarate reductase, which is helminth-specific. This action may be considered secondary to the effect on the microtubules due to decreased absorption of glucose. This action occurs in the presence of reduced amounts of nicotinamide-adenine dinucleotide in reduced form (NADH), which is a coenzyme involved in many cellular oxidation-reduction reactions.

Albendazole has larvicidal effects in necatoriasis and ovicidal effects in ascariasis, ancylostomiasis, and trichuriasis.

❖ How much strength of MESIN-C 200 mg/ 5 mL Oral Suspension?

MESIN-C 200 mg/ 5 mL Oral Suspension is available in 10 mL Glass Bottle – Yellow, liquid suspension with pineapple and peach flavor.

❖ What is MESIN-C 200 mg/ 5 mL Oral Suspension for?

Used in the treatment of Hydatid disease; Neurocysticercosis; Ascariasis; Capillariasis; Cutaneous larva migrans; Enterobiasis; Hookworm infections; Strongyloidiasis; Taeniasis; Trichostrongyliasis; Trichuriasis

❖ How much and how often should you use MESIN-C 200 mg/ 5 mL Oral Suspension?

Usual adult and adolescent dose:

Ascariasis, Enterobiasis, Hookworm infections, Trichuriasis: Oral, 400 mg as a single dose for one day. Treatment may be repeated in three weeks.

Capillariasis: Oral, 200 mg two times a day for ten days.

Cutaneous larva migrans: Oral, 400 mg once a day for three days.

Hydatid disease: Oral, 800 mg per day for twenty-eight days. Treatment may be repeated as necessary. Up to two or three cycles of Albendazole treatment may be given. For inoperable hydatid cysts, up to five cycles may be given.

Note: In hydatid disease, the dose of Albendazole for patients under 60 Kg of body weight is 12 mg per Kg of body weight per day.

Neurocysticercosis: Oral, 15 mg per Kg of body weight per day for thirty days. Treatment may be repeated as necessary.

Strongyloidiasis or Taeniasis: Oral, 400 mg as a single dose per day for three days. Treatment may be repeated in three weeks.

Trichostrongyliasis: Oral, 400 mg as a single dose.

PROPOSED PATIENT INFORMATION LEAFLET
(MALAYSIA)



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Note: In the treatment of giardiasis, an oral dose of 400 mg per day for five days has been used.

Usual pediatric dose:

Ascariasis or Enterobiasis or Hookworm infections or Trichuriasis: Children up to 2 years of age: Oral, 200 mg as a single dose for one day. Treatment may be repeated in three weeks; Children 2 years of age and over: See Usual adult and adolescent dose

Capillariasis or Neurocysticercosis or Trichostrongylasis: See Usual adult and adolescent dose.

Cutaneous larva migrans: Children: Oral, 5 mg per Kg of body weight per day for three days.

Hydatid disease: Children up to 6 years of age: Dosage has not been established; Children 6 years of age and over: Oral, 10 to 15 mg per Kg of body weight per day for twenty eight days. Treatment may be repeated as necessary.

Strongyloidiasis or Taeniasis: Children up to 2 years of age: Oral, 200 mg as a single dose per day for three consecutive days. Treatment may be repeated in three weeks; Children 2 years of age and over: See Usual adult and adolescent dose.

Note: In the treatment of *giardiasis*, see Usual adult and adolescent dose.

❖ **When should you not take MESIN-C 200 mg/ 5 mL Oral Suspension?**

Patient with Cysticercosis involving the retina; Hepatic function impairment, such as in hepatic cirrhosis.

❖ **What are the possible side effects of MESIN-C 200 mg/ 5 mL Oral Suspension?**

Incidence more frequent

Abnormal liver function test results

Incidence rare

Hypersensitivity, neutropenia – with high doses, reversible.

❖ **What other medicine or food should be avoided while taking MESIN-C 200 mg/ 5 mL Oral Suspension?**

Cimetidine (Albendazole sulfoxide concentrations are increased in patients treated with cimetidine; increased concentrations are observed in bile and cystic fluid); Corticosteroids (Concurrent use with Albendazole increases steady state through concentrations of Albendazole sulfoxide); Praziquantel (Concurrent use with Albendazole increases mean plasma concentration and area under the plasma concentration-time curve of Albendazole sulfoxide).

❖ **What should you do if you miss a dose of MESIN-C 200 mg/ 5 mL Oral Suspension?**

Taking as soon as possible; not taking if almost time for next dose; not doubling doses.

❖ **How should you keep MESIN-C 200 mg/ 5 mL Oral Suspension?**

Store at temperature of not more than 30°C.

❖ **What are the signs and symptoms of MESIN-C 200 mg/ 5 mL Oral Suspension overdose?**

No symptoms of overdosage have been reported to date



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❖ **What to do when you have taken more than the recommended dosage of MESIN-C 200 mg/ 5 mL Oral Suspension?**

Since no specific antidote is known, recommended treatment of Albendazole overdose consists of the following:

To decrease absorption – Gastric lavage may be undertaken within the first 2 to 3 hours after ingestion.

Symptomatic treatment may be given.

Supportive measures such as maintaining an open airway, respiration, and circulation may be instituted. Patients in whom intentional overdose is confirmed or suspected should be referred for psychiatric consultation.

❖ **Care that should be taken when taking MESIN-C 200 mg/ 5 mL Oral Suspension?**

Carcinogenicity: Albendazole has been tested in different species of animals and has not been found to be carcinogenic or mutagenic.

Pediatrics: Limited studies on the relationship of age to the effects on the Albendazole have been performed in children up to 6 years of age. Although hydatid disease is uncommon in infants and young children, no pediatrics-specific problems have been documented in infants and young children who were treated with Albendazole for hydatid disease.

Geriatrics: Appropriate studies on the relationship of age to the effects of the Albendazole have been performed in the geriatric population. However, no geriatrics-specific problems have been documented to date.

Fertility: Albendazole has not been shown to cause adverse effects on male or female fertility.

Pregnancy: Adequate and well-controlled studies in humans have not been done. However, Albendazole is not recommended in pregnant women because of its teratogenic effects in animals. FDA Pregnancy Category C.

Breast-feeding: Albendazole is distributed into the milk of lactating animals. It is not known

whether Albendazole is distributed into human breast milk. However, problems in humans have not been documented.

When should you consult your doctor?
See Possible Side Effects.

MESIN-C 200 mg/ 5 mL Oral Suspension is manufactured by:

UNISON LABORATORIES COMPANY, LIMITED
30 Ladkrabung Rd.,
Ladkrabung, Bangkok 10520 THAILAND

❖ **Imported and Distributed by:**

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