**MEBENDAZOLE (Systemic)**

Category

Anthelmintic (systemic).

**Indications**

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling.

Accepted

Ascariasis (treatment)¾Mebendazole is indicated as a primary agent for ascariasis caused by Ascaris lumbricoides (common roundworm). 2, 7, 8, 10, 18

Enterobiasis (treatment)¾Mebendazole is indicated as a primary agent for enterobiasis caused by Enterobius vermicularis (pinworm). 2, 7, 8, 10

Hookworm infection (treatment)¾Mebendazole is indicated as a primary agent for hookworm disease caused by Ancylostoma duodenale (common hookworm; Old World hookworm) and Necator americanus (American hookworm; New World hookworm). 2, 7, 8, 10

Intestinal roundworm, multiple (treatment)¾Mebendazole is indicated in the treatment of multiple intestinal roundworm infections. 7, 8

Trichuriasis (treatment)¾Mebendazole is indicated as a primary agent for trichuriasis caused by Trichuris trichiura (whipworm). 2, 7, 8, 10, 18

[Capillariasis (treatment)] *¾Mebendazole is used in the treatment of capillariasis caused by Capillaria philippinensis. 11, 20

[Gnathostomiasis (treatment)] *¾Mebendazole is used in the treatment of gnathostomiasis caused by Gnathostoma spinigerum. 20

[Hydatid disease, alveolar (treatment) ] *¾Mebendazole is used in the treatment of alveolar hydatid disease caused by Echinococcus multilocularis (E. alveolaris). 11

[Hydatid disease, unilocular (treatment) ] *¾Mebendazole is used in the treatment of unilocular hydatid disease caused by E. granulosus . Mebendazole is used as a secondary agent in patients in whom surgery is contraindicated or has failed, in after-spill during surgery, or in recurrences. Very high doses may be effective. 11

[Trichinosis (treatment)] *¾Mebendazole is used as a secondary agent in the treatment of trichinosis (trichinellosis) caused by Trichinella spiralis (pork worm). Systemic corticosteroids are used concurrently, especially in patients with severe symptoms, to minimize inflammatory reactions to Trichinella larvae. 1, 4, 11

Not all species or strains of a particular helminth may be susceptible to mebendazole. In addition, efficacy varies with respect to pre-existing diarrhea, gastrointestinal transit time, and degree of infection.

* Not included in Canadian product labeling.

Pharmacology

Mechanism of action/Effect:

Vermicidal; may also be ovicidal for ova of most helminths; mebendazole causes degeneration of parasite's cytoplasmic microtubules and thereby selectively and irreversibly blocks glucose uptake in susceptible adult intestine-dwelling helminths and their tissue-dwelling larvae; inhibition of glucose uptake apparently results in depletion of the parasite's glycogen stores; this, in turn, results in reduced formation of adenosine triphosphate (ATP) required for survival and reproduction of the helminth; corresponding energy levels are gradually reduced until death of the parasite ensues; mebendazole does not appear to affect serum glucose concentrations in humans, however. 11

**Precautions to Consider**

Carcinogenicity

Carcinogenicity studies in mice and rats given doses as high as 40 mg per kg of body weight (mg/kg) daily for over two years have not shown mebendazole to be carcinogenic. 7

Mutagenicity

Dominant lethal mutation studies in mice given single doses as high as 640 mg/kg have not shown that mebendazole is mutagenic. The spermatocyte test, the F 1 translocation test, and the Ames test produced negative results. 7

Pregnancy/Reproduction

Fertility¾Studies in mice given doses of up to 40 mg/kg for 60 days prior to gestation in males and 14 days in females have not shown that mebendazole causes adverse effects on the fetus or offspring. However, mebendazole has been shown to cause slight maternal toxicity at this dose. 7

Pregnancy¾Mebendazole crosses the placenta. A post-marketing survey in pregnant women who inadvertently took mebendazole during the first trimester has not shown an incidence of spontaneous abortion or malformation greater than that of the general population. In a total of 170 deliveries at term, mebendazole has not been shown to be teratogenic in humans. 7

Studies in rats given single oral doses as low as 10 mg/kg have shown that mebendazole is teratogenic and embryotoxic.
FDA Pregnancy Category C.

Breast-feeding

It is not known whether mebendazole is distributed into breast milk. However, problems in humans have not been documented.

Pediatrics

Appropriate studies on the relationship of age to the effects of mebendazole have not been performed in children up to 2 years of age. However, no pediatrics-specific problems have been documented to date in children over the age of 2. 7

Geriatrics

No information is available on the relationship of age to the effects of mebendazole in geriatric patients.

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)¾not necessarily inclusive (>> = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.
Carbamazepine 3, 5

(in patients receiving high doses of mebendazole for treatment of tissue-dwelling organisms such as Echinococcus multilocularis or E. granulosus [hydatid disease], carbamazepine has been shown to lower mebendazole plasma concentrations by induction of hepatic microsomal enzymes and to impair the therapeutic response; if carbamazepine is being used for seizures, replacement with valproic acid is recommended; treatment of intestinal helminths such as whipworms or hookworms does not appear to be affected by the rate of hepatic metabolism of mebendazole)

Laboratory value alterations

The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate)¾not necessarily inclusive (>> = major clinical significance):
With physiology/laboratory test values

>> Alanine aminotransferase (ALT [SGPT]), serum, and

>> Alkaline phosphatase, serum, and

>> Aspartate aminotransferase (AST [SGOT]), serum, and

Blood urea nitrogen (BUN)

(values may be transiently increased 12, 15 )

Hemoglobin, serum

(concentration may be decreased  15 )

**Medical considerations/Contraindications**

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¾ not necessarily inclusive (>>  = major clinical significance).
Risk-benefit should be considered when the following medical problems exist

Crohn's ileitis or

Ulcerative colitis

(may increase absorption and toxicity of mebendazole, especially in high-dose therapy)

>>  Hepatic function impairment

(mebendazole is metabolized primarily in liver; prolonged half-life and drug accumulation may occur, with an increased incidence of side effects; dosage may need to be decreased  13,  16 )

Hypersensitivity to mebendazole

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; >>  = major clinical significance):
For pinworms

>>  Perianal examinations

(cellophane tape swabs of the perianal area to detect the presence of eggs may be required prior to and starting 1 week following treatment with mebendazole, especially in patients with persisting symptoms; swabs should be taken every morning prior to defecation and bathing for at least 3 days to determine efficacy or proof of cure; perianal examinations may also be required to detect the presence of adult worms in the perianal area; no patient should be considered cured unless perianal swabs have been negative for 7 consecutive days)

For roundworms, whipworms, and capillariasis

>>  Stool examinations

(may be required prior to and approximately 1 to 3 weeks following treatment with mebendazole to determine efficacy or proof of cure; because of colonic mixing, eggs may persist in the stool for up to 1 week following cure)

For patients on high-dose therapy

>> Complete blood counts (CBCs)

(may be required prior to and periodically during the first month of treatment with mebendazole since high-dose mebendazole may cause granulocytopenia, neutropenia, and/or leukopenia; CBC's performed two or three times a week from day 10 through day 25, and weekly thereafter, are recommended)

**Side/Adverse Effects**

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:
Those indicating need for medical attention

Incidence rare

Hypersensitivity (fever; skin rash or itching) 15, 16; neutropenia (sore throat and fever; unusual tiredness and weakness)¾with high doses, reversible 12, 15, 17

Those indicating need for medical attention only if they continue or are bothersome

Incidence less frequent

Gastrointestinal disturbances (abdominal pain or upset; diarrhea; nausea or vomiting) 7, 11

Incidence rare

Alopecia (hair loss)¾with high doses 12, 15, 17; dizziness 15; headache 15

Overdose

For more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center Listing ).
In accidental overdose, gastrointestinal symptoms may occur and may last up to a few hours. 19

Treatment of overdose

Supportive care¾
Supportive therapy necessary to maintain the vital functions of the patient may be administered. 19

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Mebendazole (Systemic).
In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):
Before using this medication

>> Conditions affecting use, especially:

Hypersensitivity to mebendazole

Pregnancy¾Mebendazole crosses the placenta
Other medical problems, especially hepatic function impairment
Proper use of this medication

Reading patient instructions before taking medication

No special preparations or other measures (e.g., dietary restrictions or fasting, concurrent medications, purging, or cleansing enemas) required before, during, or immediately after therapy 7

Chewing tablets, swallowing whole, or crushing tablets and mixing with food 7

>> Compliance with full course of therapy; second course may be required in some infections

>> Proper dosing
Missed dose: Taking as soon as possible; not taking if almost time for next dose; not doubling doses
>> Proper storage
For pinworms

Treating all household members concurrently; treating again in 2 to 3 weeks

For patients on high-dose therapy

>> Taking with meals, especially fatty ones, to increase absorption; checking with physician if on low-fat diet

Precautions while using this medication

Regular visits to physician to check progress, especially in high-dose therapy

Checking with physician if no improvement within a few days

For hookworms or whipworms

Importance of taking iron supplements daily during treatment and for up to 6 months following treatment if patient is anemic at the time of therapy

For pinworms

Washing (not shaking) all bedding and nightclothes after treatment to prevent reinfection

Other measures may be recommended by some physicians

Side/adverse effects

Signs of potential side effects, especially hypersensitivity and neutropenia

General Dosing Information

No special preparations (e.g., dietary restrictions or fasting, concurrent medications, purging, or cleansing enemas) are required before, during, or immediately after treatment with mebendazole.
Mebendazole tablets may be chewed, swallowed whole, or crushed and mixed with food.
Patients who are heavily infected with helminths may require more prolonged treatment.
For high-dose therapy

In the treatment of tissue-dwelling helminth infections, the administration of much higher doses of mebendazole may be necessary because of poor absorption.
Mebendazole should preferably be taken with meals, especially fatty ones. This increases the bioavailability, absorption, and serum concentrations of mebendazole.
For hookworms and whipworms

In the treatment of hookworms and whipworms, especially in patients who are heavily infected or who have inadequate dietary intake of iron, concurrent iron therapy may be required if anemia is present. Iron therapy may need to be continued for up to 6 months to replenish iron stores.
For pinworms

Because of the high probability of transfer of pinworms, it is usually recommended that all members of the household be treated concurrently. Retreatment is recommended 2 to 3 weeks following initial treatment.

Oral Dosage Forms

Note: Bracketed uses in the Dosage Forms section refer to categories of use and/or indications that are not included in U.S. product labeling.

MEBENDAZOLE TABLETS (CHEWABLE) USP

Usual adult and adolescent dose

Ascariasis; or
Trichuriasis; or
Hookworm¾
Oral, 100 mg two times a day, morning and evening, for three days. May be repeated in two to three weeks if required. 7, 8

Enterobiasis¾
Oral, 100 mg as a single dose. Repeat in two to three weeks. 7, 8

Intestinal roundworm, multiple¾
Oral, 100 mg two times a day, morning and evening, for three days. 4

[Capillariasis] *¾
Oral, 200 mg two times a day for twenty days. 11, 20

[Gnathostomiasis] *¾
Oral, 200 mg every three hours for six days. 20

[Hydatid disease] *¾
Oral, 13.3 to 16.7 mg per kg of body weight three times a day for up to three to six months. 11

[Trichinosis] *¾
Oral, 200 to 400 mg three times a day for three days, then 400 to 500 mg three times a day for ten days. 4

Usual adult prescribing limits

[Hydatid disease] *¾Doses up to 200 mg per kg of body weight daily have been used.

Usual pediatric dose

Children up to 2 years of age¾Dosage has not been established.
Children 2 years of age and over¾Ascariasis, [capillariasis] * , enterobiasis, intestinal roundworm infections, 4 trichuriasis, and uncinariasis: See Usual adult and adolescent dose.

Note: In the treatment of infections caused by tissue-dwelling organisms in which high doses are required, dosage should be based on the patient's body weight.

Strength(s) usually available

U.S.¾ 2, 7, 10, 15, 21

100 mg (Rx)[Vermox] [Generic]

Canada¾100 mg (Rx)[Vermox (scored)] 8

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a well-closed container.

Auxiliary labeling:

· May be chewed, crushed, or swallowed whole.
· Take with meals (high-dose therapy).
· Continue medication for full time of treatment.