ALBENDAZOLE b (Systemic)

Commonly used brand name(s):Albenza; Eskazole; Zentel.

Note: For a listing of dosage forms and brand names by country availability, see Dosage Forms section(s).

Category

Anthelmintic 1, 2, 3, 4, 5, 6, 7, 8 (systemic).

Indications

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling. In addition, because albendazole is not commercially available in Canada, the use of the superscript 1 in this monograph reflects the lack of labeled (approved) indications for this medication.

General considerations

Albendazole is a broad-spectrum anthelmintic. 1, 6, 7, 10, 18, 19, 20, 31, 32, 33, 58 It is structurally related to mebendazole and has similar anthelmintic activity against many helminths 8, 39.

Accepted

Hydatid disease (treatment) *¾Albendazole is used in the treatment of hydatid disease (echinococcosis) of the liver, lung, and peritoneum caused by Echinococcus granulosus (dog tapeworm) 58.

It is also used as an adjunct to surgery of hydatid cysts, either preoperatively or postoperatively, to reduce the risk of recurrence due to operative spillage. 5, 6, 7, 8, 10, 15, 17, 22, 26, 36, 38, 39, 40

Neurocysticercosis (treatment) *¾Albendazole is used in the treatment of parenchymal neurocysticercosis caused by the larval form of Taenia solium (pork tapeworm). 7, 27, 28, 29, 34, 36, 38, 39, 41, 46, 49, 50, 51, 58 It is the only agent used in the treatment of ocular neurocysticercosis. 38, 46

[Ascariasis (treatment)] *¾Albendazole is used in the treatment of ascariasis caused by Ascaris lumbricoides (roundworm). 1, 4, 6, 7, 8, 10, 19, 20, 25, 33, 36

[Capillariasis (treatment)] *¾Albendazole is used as a secondary agent in the treatment of capillariasis caused by Capillaria philippinensis. Mebendazole is preferred for the treatment of capillariasis. 6, 7, 36, 37, 38, 56, 57

[Cutaneous larva migrans] *¾Albendazole is used in the treatment of cutaneous larva migrans. 59

[Enterobiasis (treatment)] *¾Albendazole is used in the treatment of enterobiasis (oxyuriasis) caused by Enterobius vermicularis (pinworm). 1, 4, 6, 7, 8, 20, 33, 36

[Hookworm infections (treatment)] *¾Albendazole is used in the treatment of hookworm infections, such as ancylostomiasis caused by Ancylostoma duodenale (common hookworm; Old World hookworm) and necatoriasis caused by Necator americanus (American hookworm; New World hookworm). 1, 4, 6, 7, 8, 10, 19, 20, 25, 33, 36

[Strongyloidiasis (treatment)] *¾Albendazole is used in the treatment of strongyloidiasis caused by Strongyloides stercoralis. 1, 4, 6, 7, 8, 20, 25, 36

[Taeniasis (treatment)] *¾Albendazole is used as an alternative treatment for taeniasis caused by T. solium (pork tapeworm) or Taenia saginata (beef tapeworm). 1, 4, 6, 33, 34, 44, 49 Niclosamide 6,

34, 35, 36 or praziquantel 6, 34, 36, 37 is preferred for the treatment of taeniasis. 6, 34, 35, 36, 37, 49 Although albendazole is known to offer little therapeutic advantage in the treatment of taeniasis, 6, 33, 39, 45, 49 it is generally preferred in developing countries 38, 44 because it is cheaper and has a broader spectrum of anthelmintic activity than niclosamide or praziquantel. 38, 39

[Trichostrongyliasis (treatment)] *¾Albendazole is used as a secondary agent in the treatment of trichostrongyliasis caused by Trichostrongylus species. 7, 36, 37, 38 Pyrantel pamoate is preferred for the treatment of trichostrongyliasis. 6, 36

[Trichuriasis (treatment)] *¾Albendazole is used in the treatment of trichuriasis caused by Trichuris trichiura (whipworm). 1, 4, 6, 7, 8, 10, 19, 20, 25, 33, 36

Acceptance not established

Preliminary studies suggest albendazole may be used as an alternative agent to treat giardiasis caused by Giardia species. 31, 33, 34, 42, 48, 49, 53, 55 However, data are limited 53 and results of recent clinical evaluations have shown variable efficacy of albendazole for this indication. 42, 55 Metronidazole or quinacrine is generally preferred in the treatment of giardiasis. 6, 35, 36, 40

Albendazole is used as an experimental therapeutic agent in trichinosis caused by Trichinella spiralis. 6, 7, 36, 38, 52, 53 Currently, there are insufficient data to establish efficacy of albendazole for this indication. Mebendazole is preferred for the treatment of trichinosis. 6, 36, 57

Albendazole has been used for treatment of toxocariasis . However, data to establish the efficacy of albendazole for this indication are limited. 59

* Not included in Canadian product labeling.

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Molecular weight¾265.34 [3, 8, 58]

Mechanism of action/Effect:

Vermicidal; albendazole 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 of the helminth. Due to diminished energy production, the parasite is immobilized and eventually dies. [6, 7, 9, 12, 30, 31]

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 the 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. [2, 30]

Albendazole has larvicidal effects in necatoriasis [1, 6, 32] and ovicidal effects in ascariasis, ancylostomiasis, and trichuriasis. [1, 6]

Absorption:

Poorly and erratically absorbed from the gastrointestinal tract. [2, 7] Absorption of albendazole is greatly increased if the medication is taken with food containing relatively high concentrations of fat. [2, 58]

Distribution:

Widely distributed throughout the body into bile, cerebrospinal fluid (CSF), fluid in hydatid cysts, liver, serum, and urine. 6, 8, 9, 10, 12, 58

Protein binding:

High (70%). 8, 33, 58

Biotransformation:

Hepatic; rapidly and extensively metabolized mainly to the active metabolite, albendazole sulfoxide, which appears in the systemic circulation at detectable concentrations. 2, 6, 7, 10, 30, 58 Albendazole is also metabolized to the 6-hydroxy sulfoxide and sulfone metabolites, but not in sufficient quantities to be detected consistently in the plasma. 2

Half-life:

Single dose¾ 400 mg: Approximately 8 to 12 hours. 2, 6, 7, 8, 58

15 mg/kg: Approximately 10 to 15 hours. 11

Time to peak concentration:

Single dose¾ 400 mg: Approximately 2 to 5 hours. 2, 6, 58

15 mg/kg: Approximately 4 hours. 11

Peak serum concentration:

Single dose¾ 400 mg: Approximately 0.46 to 1.58 mcg/mL 58.

15 mg/kg: Approximately 0.45 to 2.96 mcg/mL. 11

Elimination:

Renal¾Approximately 1% is excreted in the urine as albendazole sulfoxide during the first 24 hours. 58 Other metabolites also are renally excreted. 2, 6, 7, 8

Fecal¾A small amount is found in the feces. 6

Precautions to Consider

Carcinogenicity/Mutagenicity

Albendazole has been tested in different species of animals and has not been found to be carcinogenic or mutagenic. 2

Pregnancy/Reproduction

Fertility¾Albendazole has not been shown to cause adverse effects on male or female fertility. 2, 58

Pregnancy¾Adequate and well-controlled studies in humans have not been done. However, albendazole is not recommended for use in pregnant women 1, 2, 4 because of its teratogenic effects in animals. 1, 4, 5, 6, 7, 30, 31, 58 For women of childbearing age, it is recommended that albendazole be administered within 7 days after the start of normal menstruation. 1, 4, 7 Following a negative

pregnancy test, contraceptive measures must be used for the duration of treatment and for 1 month after cessation of treatment. 2, 5

Albendazole was teratogenic 1, 4, 5, 6, 7, 19, 30, 31, 58 (embryotoxicity and skeletal malformations) in pregnant rats and rabbits. Teratogenicity occurred in rats given oral doses of 10 and 30 mg per kg of body weight (mg/kg) per day during gestation days 6 to 15 and in rabbits given oral doses of 30 mg/kg per day during gestation days 7 to 19. In the rabbit study, maternal toxicity (33% mortality) was noted at 30 mg/kg per day. However, no teratogenic effects were observed in mice given oral doses of up to 30 mg/kg per day during gestation days 6 to 15 58.

FDA Pregnancy Category C 58.

Breast-feeding

Albendazole is distributed into the milk of lactating animals 58.

It is not known whether albendazole is distributed into human breast milk 58.

However, problems in humans have not been documented.

Pediatrics

Limited studies on the relationship of age to the effects of 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. In addition, five studies involving children as young as 1 year of age treated with albendazole for neurocysticercosis, which occurs more frequently than hydatid disease in children, did not document pediatrics-specific problems. 58

Geriatrics

Appropriate studies on the relationship of age to the effects of albendazole have not been performed in the geriatric population. However, no geriatrics-specific problems have been documented to date.

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):

>> Cimetidine

(albendazole sulfoxide concentrations are increased in patients treated with cimetidine; increased concentrations are observed in bile and cystic fluid 58)

>> Corticosteroids

(concurrent use with albendazole increases steady-state trough concentrations of albendazole sulfoxide 27, 28, 34, 38, 43, 46, 58)

>> Praziquantel

(concurrent use with albendazole increases mean plasma concentration and area under the plasma concentration-time curve of albendazole sulfoxide 58)

Theophylline

(albendazole induces cytochrome P450 1A in human hepatic cells; plasma concentrations of theophylline should be monitored during and after concurrent treatment with albendazole 58)

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

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

(values may be transiently elevated 2, 9, 21, 26, 58)

>> Leukocytes (neutrophils [WBC])

(may be transiently decreased 2, 9, 19, 21, 26, 58)

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

>> Cysticercosis involving the retina

(before the initiation of therapy for neurocysticercosis, the patient should be examined for retinal lesions; benefits of the anticysticeral therapy should be weighed against the possibility of retinal damage caused by albendazole-induced changes to existing lesions 58)

>> Hepatic function impairment, such as in hepatic cirrhosis 6

(albendazole is extensively metabolized in the liver; 2, 6, 7, 10, 30 intrahepatic hemodynamics caused by a disordered liver architecture as in hepatic cirrhosis may impair the rate of hepatic clearance, thereby resulting in albendazole accumulation and an increased incidence of side effects 13)

Hypersensitivity to albendazole 7

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 ascariasis, hookworm infections, and trichuriasis

>> Stool examinations

(may be required prior to treatment to detect the presence of eggs, and approximately 1 to 3 weeks following treatment with albendazole to determine efficacy of medication or establish proof of cure 14)

For enterobiasis

>> Perianal examinations

(cellophane tape swabbing of the perianal area to detect the presence of eggs may be required prior to treatment to confirm the diagnosis of pinworms, and starting 1 week following treatment with albendazole, especially in patients with persisting symptoms; swabbing should be done every morning after getting out of bed and 34 prior to defecation and bathing for at least 3 days to determine efficacy of medication or establish proof of cure; perianal examinations also may be required to detect the presence of adult worms in the perianal area; perianal swabbings should be negative for 7 consecutive days for the patient to be considered cured 23)

For strongyloidiasis

>> Stool examinations

(routine stool examinations and special concentration examinations, preferably the Baermann technique [which is especially useful when there is a high index of suspicion for strongyloidiasis and when routine stool examinations are negative for the organism], may be required prior to treatment to detect the presence of larvae, and repeated at intervals of 3 months along with clinical assessment of the patient, beginning at 6 weeks after completion of treatment with albendazole, to determine efficacy of the medication or establish proof of cure; however, determination of cure may be difficult since the parasite is not easily eradicated and, therefore, re-treatment may be necessary 9, 34, 49, 53, 57)

For taeniasis

>> Cellophane tape swabbing 34, 44 or

>> Stool examinations

(may be required prior to treatment to detect the presence of eggs or proglottids, and approximately 3 and 6 months following treatment to determine efficacy of medication or establish proof of cure 14)

For patients on long-term therapy

>> Complete blood counts (CBCs) and

>> Liver function tests

(since albendazole may cause a reduction in total white cell counts and an elevation in hepatic enzymes with prolonged use, it is recommended that blood counts and liver function tests be carried out prior to treatment and every 2 weeks during treatment with albendazole; re-treatment should not be initiated if significant depression in total white cell counts or elevation in liver enzymes persists 2, 5, 58)

Theophylline concentration

(plasma concentrations of theophylline should be monitored during and after albendazole treatment because albendazole induces cyctochrome P450 1A in human hepatic cells 58)

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 more frequent

Abnormal liver function test results 58

Incidence rare

Hypersensitivity (fever; skin rash or itching) 2, 5, 9, 20, 24, 25, 26; neutropenia (sore throat and fever; unusual tiredness and weakness) 2, 5, 19, 21¾with high doses, reversible 2, 5

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

Incidence less frequent

Central nervous system (CNS) effects (dizziness; headache) 2, 4, 5, 6, 7, 9, 20, 25, 26, 33, 58; gastrointestinal disturbances (abdominal pain; diarrhea; nausea; vomiting) 1, 2, 4, 5, 6, 7, 9, 20, 25, 26, 33, 58

Incidence rare

Alopecia (thinning of hair or moderate hair loss)¾reversible 2, 5, 9, 21, 26, 58

Overdose

For more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center Listing).

Treatment of overdose

Since no specific antidote is known, recommended treatment of albendazole overdose consists of the following: 5, 7

To decrease absorption¾Gastric lavage may be undertaken within the first 2 to 3 hours after ingestion.

Symptomatic treatment may be given. 58

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.

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Albendazole (Systemic) .

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Hypersensitivity to albendazole

Pregnancy¾Not recommended for use in pregnancy because albendazole has been found to be teratogenic in animals; for women of childbearing age, taking the medication within 7 days after the start of normal menstruation; 1, 4 after a negative pregnancy test, using contraceptive measures during treatment and for 1 month after cessation of treatment 2, 5, 58

Other medications, especially cimetidine, corticosteroids, and praziquantel

Other medical problems, especially cysticercosis involving the retina and hepatic function impairment

Proper use of this medication

No specific procedures such as fasting or purging or other measures are required before, during, or immediately after treatment with albendazole 1

>> Taking with food containing fat to increase absorption 2, 5, 6, 58

Proper administration for tablet dosage form¾Swallowing whole with a small amount of liquid 1

>> Compliance with full course of therapy; treatment program may be repeated in 2 to 3 weeks for heavy infection [1, 4]

>> Proper dosing

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

>> Proper storage

Precautions while using this medication

Regular visits to physician to check progress

Checking with physician if no improvement after the full course of treatment or if symptoms persist

For women of childbearing age, using contraception since albendazole has been found to be embryotoxic and teratogenic in animals

Side/adverse effects

Signs of potential side effects, especially abnormal liver function test results, hypersensitivity, and neutropenia [2, 5]

General Dosing Information

Patients who are heavily infected with helminths may require a second treatment. [1, 4]

If giardiasis is present, asymptomatic patients may be treated with albendazole to prevent spread of infection to others. Parasitologic and clinical relapse of giardiasis may occur after the completion of therapy; long-term follow-up with the physician may be necessary. [14]

If using albendazole to treat trichinosis, concurrent use of corticosteroids may be required to alleviate the allergic and inflammatory symptoms. 6, 7, 14 However, concurrent use with corticosteroids may alter the trough concentrations for steady-state 58.

For enterobiasis

Because of the high probability of transfer of pinworms, it is usually recommended that all members of the household be treated simultaneously. 23

For neurocysticercosis

Corticosteroids have been shown to increase the plasma levels of albendazole. 27, 28, 34, 38, 43, 46 Concurrent use may be required to relieve the exacerbated symptoms due to the inflammatory response around the dying parasites and should be considered to prevent cerebral hypertension during the first week of treatment. 6, 27, 28, 29, 58

Patients should receive anticonvulsant therapy as required. 58

Oral Dosage Forms

ALBENDAZOLE ORAL SUSPENSION

Note: Because albendazole oral suspension is not commercially available in the U.S. or Canada, the bracketed uses and the use of the superscript 1 in this section reflect the lack of labeled (approved) indications for this medication in these countries.

Usual adult and adolescent dose

[Ascariasis] * or

[Enterobiasis] * or

[Hookworm infections] * or

[Trichuriasis] *¾Oral, 400 mg as a single dose for one day. 1, 2, 4, 6, 33, 36 Treatment may be repeated in three weeks. 1, 4

[Capillariasis] *¾Oral, 200 mg two times a day for ten days. 6, 9, 36

[Cutaneous larva migrans] *¾Oral, 400 mg once a day for three days 59.

[Hydatid disease] *¾Oral, 800 mg per day for twenty-eight days. 2, 5, 6, 36 Treatment may be repeated as necessary. 34, 36 Up to two or three cycles of albendazole treatment may be given. 2, 5, 6 For inoperable hydatid cysts, up to five cycles may be given. 10

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. 5

[Neurocysticercosis] *¾Oral, 15 mg per kg of body weight per day for thirty days. 6, 7, 9, 29 Treatment may be repeated as necessary.

[Strongyloidiasis] * or

[Taeniasis] *¾Oral, 400 mg as a single dose per day for three days. 1, 4, 33 Treatment may be repeated in three weeks. 1, 4

[Trichostrongyliasis] *¾Oral, 400 mg as a single dose. 7, 36

Note: In the treatment of giardiasis, an oral dose of 400 mg per day for five days has been used. 53

Usual pediatric dose

[Ascariasis] * or

[Enterobiasis] * or

[Hookworm infections] * or

[Trichuriasis] *¾Children up to 2 years of age: Oral, 200 mg as a single dose for one day. Treatment may be repeated in three weeks. 1, 4

Children 2 years of age and over: See Usual adult and adolescent dose. 1, 4

[Capillariasis] * or

[Neurocysticercosis] * or

[Trichostrongyliasis] *¾See Usual adult and adolescent dose. 36, 53

[Cutaneous larva migrans] *¾Children: Oral, 5 mg per kg of body weight per day for three days 59.

[Hydatid disease] *¾Children up to 6 years of age: Dosage has not been established. 5

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. 2, 5, 36, 53

[Strongyloidiasis] * or

[Taeniasis] *¾Children 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. 1, 4

Children 2 years of age and over: See Usual adult and adolescent dose. 1, 4

Note: In the treatment of giardiasis, see Usual adult and adolescent dose. 42, 53

Strength(s) usually available

U.S.¾Not commercially available.

Canada¾Not commercially available.

United Kingdom¾100 mg per 5 mL (Rx)[Zentel 1, 4]

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from freezing and direct sunlight. 1, 4, 5

Auxiliary labeling:

- Shake well.
- Take with meals.
- Continue medication for full time of treatment.

ALBENDAZOLE TABLETS

Note: Because albendazole tablets are not commercially available in Canada, the use of the superscript 1 in this section reflects the lack of labeled (approved) indications for this medication in Canada.

Usual adult and adolescent dose

Hydatid disease *¾Adults and adolescents weighing 60 kg or more: Oral, 400 mg two times a day for twenty-eight days. Treatment may be repeated in fourteen days. Up to three cycles of albendazole treatment may be given. 58

Adults and adolescents weighing less than 60 kg: Oral, 15 mg per kg of body weight per day, given in divided doses two times a day for twenty-eight days. Treatment may be repeated in fourteen days. Up to three cycles of albendazole treatment may be given. 58

Note: To achieve optimal killing of the cysts, albendazole is best given as three courses of therapy in a presurgical or postsurgical setting. 58

Neurocysticercosis *¾Adults and adolescents weighing 60 kg or more: Oral, 400 mg two times a day for eight to thirty days. 58

Adults and adolescents weighing less than 60 kg: Oral, 15 mg per kg of body weight per day, given in divided doses two times a day for eight to thirty days. 58

[Ascariasis] * or

[Capillariasis] * or

[Enterobiasis] * or

[Hookworm infections] * or

[Strongyloidiasis] * or

[Taeniasis] * or

[Trichostrongyliasis] * or

[Trichuriasis] *¾See Albendazole Oral Suspension.

[Cutaneous larva migrans] *¾Oral, 400mg once a day for three days 59.

Note: In the treatment of giardiasis, see Albendazole Oral Suspension. 42, 53

Usual adult and adolescent prescribing limits

800 mg for patients weighing less than 60 kg 58.

Usual pediatric dose

Hydatid disease * or

Neurocysticercosis *¾See Usual adult and adolescent dose .

[Ascariasis] * or

[Capillariasis] * or

[Cutaneous larva migrans] * or

[Enterobiasis] * or

[Hookworm infections] * or

[Strongyloidiasis] * or

[Taeniasis] * or

[Trichostrongyliasis] * or

[Trichuriasis] *¾See Albendazole Oral Suspension. 1, 4, 36

Note: In the treatment of giardiasis, see Albendazole Oral Suspension. 42, 53

Usual pediatric prescribing limits

Maximum total daily dose for patients weighing less than 60 kg is 800 mg. 58

Strength(s) usually available

U.S.¾200 mg (Rx)[Albenza (carnauba wax) (hydroxypropyl methylcellulose) (lactose monohydrate) (magnesium stearate) (microcrystalline cellulose) (povidone) (sodium lauryl sulfate) (sodium saccharin) (sodium starch glycolate) (starch) 58]

Canada¾Not commercially available.

United Kingdom¾200 mg (Rx)[Zentel] 1, 4

400 mg (Rx)[Eskazole (scored)] 2, 15, 54

Packaging and storage:

Store between 20 and 25 °C (68 and 77 °F), in a well-closed container, unless otherwise specified by manufacturer. Protect from direct sunlight. 58

Auxiliary labeling:

- Tablets should be swallowed whole.
- Take with meals.
- Continue medication for full time of treatment.

References

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