

Albendazole Tablets USP, 200 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Albendazole tablets are indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, <i>Taenia solium</i> and are indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, <i>Echinococcus granulosus</i> .
2	Dosage	What is the recommended dosage?	Hydatid Disease: For patients with weight 60kg or above 60kg, dose to given is 400mg twice daily with meals and for patients with less than 60kg, dose to be given is 15 mg/kg/day given in divided doses twice daily with meals (maximum total daily dose 800 mg) for 28-day cycle followed by a 14-day albendazole - free interval, for a total of 03 cycles. Neurocysticercosis: For patients with weight 60kg or above 60kg, dose to be given is 400 mg twice daily, with meals and for patients with weight less than 60kg, 15 mg/kg/day to be given in divided doses twice daily with meals (maximum total daily dose 800 mg) for 8 to 30 days.
3	Administration	How do I take it?	Albendazole tablets should be taken with food.
4	Formulation	Can tablet be crushed?	Albendazole tablets may be crushed or chewed and swallowed with a drink of water.
5	Administration	What do I do if I miss a dose?	If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time. Please contact your physician for further queries.
6	Administration	Use in Pediatric Population	Hydatid disease is uncommon in infants and young children. In neurocysticercosis, the efficacy of albendazole in children appears to be similar to that in adults.
7	Administration	Use in Geriatric Population	In patients aged 65 and older with either hydatid disease or neurocysticercosis, there was insufficient data to determine whether the safety and effectiveness of albendazole is different from that of younger patients
8	Mechanism	Mechanism of Action	Albendazole binds to the colchicine-sensitive site of β -tubulin inhibiting their polymerization into microtubules. The decrease in microtubules in the intestinal cells of the parasites decreases their absorptive function, especially the uptake of glucose by the adult and larval forms of the parasites, and also depletes glycogen storage. Insufficient glucose results in insufficient energy for the production of adenosine trisphosphate (ATP) and the parasite eventually dies.

9	Warning	Black Box Warning	None.
10	Lactation	Use in Lactation	Concentrations of albendazole and the active metabolite, albendazole sulfoxide, have been reported to be low in human breast milk. There are no reports of adverse effects on the breastfed infant and no information on the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for albendazole and any potential adverse effects on the breastfed infant from albendazole or from the underlying maternal condition.
11	Pregnancy	Use in Pregnancy	Pregnancy testing is recommended for females of reproductive potential prior to therapy. Albendazole may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception.
12	Precautions	Is there any interaction between medication and alcohol?	None.
13	Interaction	Is there any interaction with food?	None.
14	Side effects	What are the common side effects?	<p>Adverse reactions 1% or greater in hydatid disease: abnormal liver function tests, abdominal pain, nausea/vomiting, reversible alopecia, headache, dizziness/vertigo and fever.</p> <p>Adverse reactions 1% or greater in neurocysticercosis: headache, nausea/vomiting, raised intracranial pressure, meningeal signs.</p>
15	Storage	What are the storage conditions?	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Albendazole is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds or any components of albendazole.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	<p>"Albendazole tablets USP, 200 mg are white colored, round shaped, biconvex, film coated tablets debossed with ""MA 7"" on one side and plain on other side and contains 200 mg of albendazole.</p> <p>They are supplied as bottle of 02 tablets and bottle of 28 tablets</p> <p>NDC: 72205-051-08 NDC: 72205-051-28</p>
19	Ingredients	Active and Inactive Ingredients	<p>Active: Albendazole</p> <p>Inactive: corn starch, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K 30, sodium lauryl sulfate, sodium starch glycolate, Hypromellose, titanium dioxide, polyethylene glycol.</p>

20	Coating	What is the type of coating?	Film coated tablets
Allergens			
21	Ingredients	Is it Vegetarian?	No, Lactose produced from Milk, that has been sourced from healthy cows.
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	Yes (Lactose)
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	Yes (corn starch)
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	Yes (corn starch)
35	Ingredients	Does it contain contain povidone?	Yes
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes (present in API)
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	Yes
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			

47	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products
48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500.
49	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
50	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report SUSPECTED ADVERSE REACTIONS, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1- 800-FDA-1088 or www.fda.gov/medwatch.
51	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
52	Miscellaneous	Manufacturer and Distributor	Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA Distributed by: MSN Pharmaceuticals Inc. Piscataway, NJ 08854-3714 Issued on: 12/2019