Trientine Hydrochloride Capsules USP, 250 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Trientine hydrochloride capsules USP 250 mg i s indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine. Trientine hydrochloride capsules USP 250 mg is not indicated for treatment of biliary cirrhosis.
2	Dosage	What is the recommended dosage?	The recommended initial dose of trientine hydrochloride capsules USP 250 mg is 500 to 750 mg/day for pediatric patients and 750 to 1250 mg/day for adults given in divided doses two, three or four times daily. This may be increased to a maximum of 2000 mg/day for adults or 1500 mg/day for pediatric patients age 12 or under.
3	Administration	How to administer?	It is important that trientine hydrochloride capsules USP 250 mg be given on an empty stomach, at least one hour before meals or two hours after meals and at least one hour apart from any other drug, food, or milk.
4	Administration	Can capsule be chewed?	The capsules should be swallowed whole with water and should not be opened or chewed.
5	Administration	Use in Pediatric Population	Controlled studies of the safety and effectiveness of trientine hydrochloride in pediatric patients have not been conducted. It has been used clinically in pediatric patients as young as 6 years with no reported adverse experiences.
6	Administration	Use in Geriatric Population	Clinical studies of trientine hydrochloride capsules did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience is insufficient to determine differences in responses between the elderly and younger patients. In general, dose selection should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
7	Mechanism	Mechanism of Action	Trientine hydrochloride is a chelating compound for removal of excess copper from the body.
8	Warning	Black Box Warning	No black box warning
9	Lactation	Use in Lactation	It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when trientine hydrochloride is administered to a nursing mother.
10	Pregnancy	Use in Pregnancy	There are no adequate and well-controlled studies in pregnant women. Trientine hydrochloride should be used during pregnancy

			only if the potential benefit justifies the potential risk to the fetus.
11	Precautions	Is there any interaction between medication and alcohol.	Not available
12	Storage	What are the storage conditions?	Dispense in a tight container and store in a refrigerator; 2 to 8°C (36 to 46°F). Keep container tightly closed.
13	Dispensing	How to Dispense?	Dispense in a tight container and store in a refrigerator; 2 to 8°C (36 to 46°F). Keep container tightly closed.
14	Contraindication	What are the contraindications of (medication).	Hypersensitivity to this product.
Pharmaceutical Particulars			
15	Pharmaceutical Form	How is it supplied?	Trientine hydrochloride capsules, USP 250 mg, are capsules with light brown opaque body imprinted with “250” and light brown opaque cap imprinted with “TRN” in black ink. They are supplied as follows: NDC 72205–008-91 in bottles of 100.
16	Ingredients	Active and Inactive	Trientine hydrochloride capsules USP 250 mg contains gelatin, iron oxide black, iron oxide red, iron oxide yellow, potassium hydroxide, propylene glycol, shellac, stearic acid and titanium dioxide as inactive ingredients.
Allergens			
17	Ingredients	Does it contain Gluten?	No
18	Ingredients	Does it contain alcohol?	No
19	Ingredients	Does it contain dyes?	No
20	Ingredients	Does it contain Lactose?	No
21	Ingredients	Does it contain Nuts?	No
22	Ingredients	Does it contain Preservatives?	No
23	Ingredients	Does it contain Soy products?	No
24	Ingredients	Does it contain peanut?	No
25	Ingredients	Are all excipients are free from human or animal origin?	No. Gelatin is used in Capsule shell
Miscellaneous			
26	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
27	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
28	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.

29	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.
30	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
31	Miscellaneous	May I know where is this product manufactured?	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714