

Tiagabine Hydrochloride Tablets, 2 mg, 4 mg, 12 mg and 16 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Tiagabine hydrochloride tablet is indicated as adjunctive therapy in adults and children of 12 years and older in the treatment of partial seizures.
2	Dosage	What is the recommended dosage?	<p>In adolescents 12 to 18 years old, tiagabine hydrochloride tablets should be initiated at 4 mg once daily. The total daily dose of tiagabine hydrochloride tablets may be increased by 4 mg at the beginning of Week 2. Thereafter, the total daily dose may be increased by 4 to 8 mg at weekly intervals until clinical response is achieved or up to 32 mg/day. The total daily dose should be given in divided doses two to four times daily.</p> <p>In adults, tiagabine hydrochloride tablets should be initiated at 4 mg once daily. The total daily dose of tiagabine hydrochloride tablets may be increased by 4 to 8 mg at weekly intervals until clinical response is achieved or, up to 56 mg/day. The total daily dose should be given in divided doses two to four times daily.</p> <p>For dose modifications taking into account of concomitant medications, please refer to complete PI.</p>
3	Administration	How do I take it?	Tiagabine hydrochloride tablet is given orally and should be taken with food. Take tiagabine hydrochloride tablets exactly as your healthcare provider tells you.
4	Formulation	Can tablet be crushed?	Tiagabine hydrochloride tablet is given orally and should be taken with food. Take tiagabine hydrochloride tablets exactly as your healthcare provider tells you.
6	Administration	Use in Pediatric Population	Safety and effectiveness in pediatric patients below the age of 12 have not been established.
7	Administration	Use in Geriatric Population	The pharmacokinetic profile of tiagabine was similar in healthy elderly and healthy young adults.
8	Mechanism	Mechanism of Action	The precise mechanism by which tiagabine exerts its antiseizure effect is unknown. It is believed that tiagabine blocks GABA uptake into presynaptic neurons, permitting more GABA to be available for receptor binding on the surfaces of postsynaptic cells.
9	Warning	Black Box Warning	No black box warning
10	Lactation	Use in Lactation	Before taking tiagabine hydrochloride tables, tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if tiagabine hydrochloride passes into breast milk or if it can

			harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take tiagabine hydrochloride tablets.
11	Pregnancy	Use in Pregnancy	<p>Before taking tiagabine hydrochloride tablets, tell your healthcare provider if you are pregnant or plan to become pregnant. It is not known if tiagabine hydrochloride tablets can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking tiagabine hydrochloride tablets. You and your healthcare provider will decide if you should take tiagabine hydrochloride tablets while you are pregnant.</p> <p>If you become pregnant while taking tiagabine hydrochloride tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy. You can enroll in this registry by calling 1-888-233-2334. There are no adequate and well-controlled studies in pregnant women. Tiagabine should be used during pregnancy only if clearly needed</p>
12	Precautions	Is there any interaction between medication and alcohol?	It is recommended to not drink alcohol or take other medicines that make you sleepy or dizzy while taking tiagabine hydrochloride tablets without first talking to your healthcare provider. Taking tiagabine hydrochloride tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
	Precautions	Is there any effect on ability to drive and use machines?	Do not drive, operate heavy machinery, or do other dangerous activities until you know how tiagabine hydrochloride tablets affects you. Tiagabine hydrochloride tablets can slow your thinking and motor skills.
13	Interaction	Is there any interaction with food?	None.
14	Side effects	What are the common side effects?	The most common side effects of tiagabine hydrochloride tablets include dizziness, lack of energy, drowsiness, nausea, nervousness, tremor, stomach pain, abnormal thinking and difficulty with concentration or attention.
15	Storage	What are the storage conditions?	Store tiagabine hydrochloride tablets between 68°F to 77°F (20°C to 25°C). Protect from light and moisture. Keep tiagabine hydrochloride tablets out of light and dry.
16	Dispensing	How to Dispense?	As prescribed by the Physician.
17	Contraindication	What are the contraindications of (medication).	Tiagabine hydrochloride is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	<p>Tiagabine hydrochloride tablets are available in four dosage strengths.</p> <ul style="list-style-type: none"> • 2 mg light orange-peach colored, round shaped, biconvex film-coated tablets debossed with “MT” on one side and “3” on the other side, are available in bottles of 30 (NDC 72205-084-30). • 4 mg yellow colored, round shaped, biconvex film-coated tablets debossed with “MT” on one side and “4” on the

			<p>other side, are available in bottles of 30 (NDC 72205-085-30).</p> <ul style="list-style-type: none"> • 12 mg green colored, capsule shaped, biconvex film-coated tablets debossed with “MT” on one side and “5” on the other side, are available in bottles of 30 (NDC 72205-086-30). • 16 mg blue colored, capsule shaped, biconvex film-coated tablets debossed with “MT” on one side and “6” on the other side, are available in bottles of 30 (NDC 72205-087-30).
19	Ingredients	Active and Inactive Ingredients	<p>Active: Tiagabine hydrochloride</p> <p>Inactive: Butylated hydroxyanisole, colloidal silicon dioxide, crospovidone, hydrogenated vegetable oil (cottonseed oil), hydroxypropyl cellulose, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, pregelatinized starch, stearic acid and titanium dioxide</p>
20	Coating	What is the type of coating?	Biconvex film coated.
Allergens			
21	Ingredients	Is it Vegetarian?	No. Lactose produced from milk, that has been sourced from healthy cows is used as an inactive ingredient.
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	Yes, Lactose produced from milk, that has been sourced from healthy cows is used as an inactive ingredient.
24	Ingredients	Does it contain Casein?	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	Yes, Starch used in this product derived from corn.
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, Starch used in this product derived from corn.
35	Ingredients	Does it contain povidone?	Yes
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No

38	Ingredients	Does it contain alcohol?	Tiagabine API and opadry color contains solvents within the limits as per guidelines.
39	Ingredients	Does it contain dyes?	Opadry colors Contains Dyes
41	Ingredients	Does it contain Lactose?	Yes, Lactose produced from Milk source from healthy cows
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	<p>Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA.</p> <p>Distributed by: Novadoz Pharmaceuticals Inc. Piscataway, NJ 08854-3714</p>