

Clobazam Tablets, 10 mg, and 20 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Clobazam tablets are a benzodiazepine indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.
2	Dosage	What is the recommended dosage?	A daily dose of clobazam tablets greater than 5 mg should be administered in divided. Doses twice daily; a 5 mg daily dose can be administered as a single dose. Dose patients according to body weight. Individualize dosing within each body weight group, based on clinical efficacy and tolerability. Please refer complete PI for more information
3	Administration	How do I take it?	Clobazam tablets can be taken with or without food.
4	Formulation	Can tablet be crushed?	Clobazam tablets can be administered whole, broken in half along the score or crushed and mixed in applesauce.
5	Administration	Use in Pediatric Population	Safety and effectiveness in patients less than 2 years of age have not been established.
6	Administration	Use in Geriatric Population	Clinical studies of clobazam did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. However, elderly subjects appear to eliminate clobazam more slowly than younger subjects based on population pharmacokinetic analysis. For these reasons, the initial dose in elderly patients should be 5 mg/day. Patients should be titrated initially to 10 to 20 mg/day. Patients may be titrated further to a maximum daily dose of 40 mg if tolerated.
7	Mechanism	Mechanism of Action	The exact mechanism of action for clobazam, a 1,5-benzodiazepine, is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA _A receptor.
8	Warning	Black Box Warning	RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; AND DEPENDENCE AND WITHDRAWAL REACTIONS. See full prescribing information for complete boxed warning.
9	Lactation	Use in Lactation	Clobazam is excreted in human milk. Post marketing experience suggests that breastfed infants of mothers taking benzodiazepines, such as clobazam, may have effects of lethargy, somnolence and poor sucking. Patients should be counseled that clobazam is excreted in breast milk. Patients should notify their physician if they are breast feeding or intend to breast feed during therapy and

			nursing mothers should be counseled to observe their infants for poor sucking and somnolence.
10	Pregnancy	Use in Pregnancy	<p>In Pregnant women and women of childbearing potential, the use of clobazam during pregnancy can cause fetal harm which may occur early in pregnancy before many women know they are pregnant.</p> <p>Patients should notify their healthcare provider if they become pregnant or intend to become pregnant during therapy. When appropriate, prescribers should counsel pregnant women and women of childbearing potential about alternative therapeutic options.</p>
11	Precautions	Is there any interaction between medication and alcohol?	<p>Do not drink alcohol while taking Clobazam tablets. clobazam tablets tablets and alcohol can affect each other and cause severe drowsiness, breathing problems (respiratory depression), coma and death.</p> <p>See full prescribing information for complete information.</p>
12	Interaction	Is there any interaction with food?	None.
13	Side effects	What are the common side effects?	<p>The most common side effects of Clobazam tablets are sleepiness, drooling, constipation, cough, pain with urination, fever, acting aggressive, being angry or violent, difficulty sleeping, slurred speech, tiredness, problems with breathing.</p> <p>See full prescribing information for more information on side effects with Clobazam</p>
14	Storage	What are the storage conditions?	Store tablets at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].
15	Dispensing	How to Dispense?	Dispense in a USP tight container.
16	Contraindication	What are the contraindications of (medication).	<p>Clobazam is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions.</p> <p>See full prescribing information for more information</p>
Pharmaceutical Particulars			
17	Pharmaceutical Form	How is it supplied?	<p>Each clobazam tablet contains 10 mg or 20 mg of clobazam and is a white to off-white, oval shaped uncoated tablet with a functional score on one side and either a "C" and "M" or a "C" and "L" debossed on the other side.</p> <p>NDC 72205-047-91: 10 mg scored tablet, Bottles of 100 NDC 72205-048-91: 20 mg scored tablet, Bottles of 100</p>
18	Ingredients	Active and Inactive Ingredients	<p>Active: clobazam</p> <p>Inactive: corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch, silicon dioxide and talc.</p>
19	Coating	What is the type of coating?	uncoated tablets
Allergens			
20	Ingredients	Is it Vegetarian?	Yes

21	Ingredients	Does it contain Gluten?	No
22	Ingredients	Does it contain Dairy Products?	Yes, Lactose produced from Milk source from healthy cows
23	Ingredients	Does it contain Casein?	No
24	Ingredients	Does it contain Whey?	No
25	Ingredients	Does it contain corn?	Yes, Starch used in this product derived from maize starch/corn starch
26	Ingredients	Does it contain rye?	No
27	Ingredients	Does it contain sugar?	No
28	Ingredients	Does it contain Oats?	No
29	Ingredients	Does it contain wheat?	No
30	Ingredients	Does it contain spelt?	No
31	Ingredients	Does it contain barley?	No
32	Ingredients	Does it contain rennet?	No
33	Ingredients	Does it contain starch?	Yes, Starch used in this product derived from maize starch/corn starch
34	Ingredients	Does it contain povidone?	No
35	Ingredients	Does it contain Iodine?	No
36	Ingredients	Does it contain latex?	No
37	Ingredients	Does it contain alcohol?	No
38	Ingredients	Does it contain dyes?	No
39	Ingredients	Does it contain flavor?	No
40	Ingredients	Does it contain Lactose?	Yes, Lactose produced from Milk source from healthy cows
41	Ingredients	Does it contain Nuts?	No
42	Ingredients	Does it contain Preservatives?	No
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No
Miscellaneous			
46	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
47	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500.

48	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
49	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 .
50	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.
51	Miscellaneous	Manufacturer and Distributor	<p>Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA.</p> <p>Distributed by: MSN Pharmaceuticals Inc. Piscataway, NJ 08854-3714</p>