NOVADOZ®
VALUE IN EVERY DOSE

Pregabalin Extended-Release Tablets, 82.5 mg, 165 mg, and 330 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Pregabalin extended-release tablets are indicated for the management of: • Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Postherpetic neuralgia (PHN)
2	Dosage	What is the recommended dosage?	Dosing recommendations for pregabalin extended-release tablets: For DPN Pain, Begin dosing at 165 mg per day with a maximum dose of 330 mg/day within 1 week For PHN, Begin dosing at 165 mg per day with a maximum dose of 330 mg/day within 1 week Dose modification recommended in patients with renal impairment.
3	Administration	How do I take it?	Take pregabalin extended-release tablets exactly as prescribed. Your healthcare provider will tell you how much pregabalin extended-release tablets to take and when to take it. Take pregabalin extended-release tablets at the same time each day. Pregabalin extended-release tablets must be taken after your evening or morning meal as recommended.
4	Formulation	Can tablet be crushed?	Swallow the tablet whole and do not split, crush or chew the tablet.
5	Administration	What do I do if I miss a dose?	If you miss a dose after your evening meal, take it prior to bedtime following a snack. If you miss the dose prior to bedtime, then take it following your morning meal. If you miss the dose of pregabalin extended-release tablets following the morning meal, then they should take their usual dose of pregabalin extended-release tablets at the usual time that evening following an evening meal. *Please contact your physician for further queries.*
6	Administration	Use in Pediatric Population	The safety and effectiveness of pregabalin extended-release tablets in pediatric patients have not been established.
7	Administration	Use in Geriatric Population	No overall differences in safety and effectiveness were observed between elderly patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

8	Mechanism	Mechanism of Action	Pregabalin binds with high affinity to the alpha$_2$ -delta site (an auxiliary subunit of voltage- gated calcium channels) in central nervous system tissues. Although the mechanism of action of pregabalin has not been fully elucidated, results with genetically modified mice and with compounds structurally related to pregabalin (such as gabapentin) suggest that binding to the alpha2-delta subunit may be involved in pregabalin's anti-nociceptive and antiseizure effects in animals. While pregabalin is a structural derivative of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), it does not bind directly to GABAA, GABAB, or benzodiazepine receptors, does not augment GABAA responses in cultured neurons, does not alter rat brain GABA concentration or have acute effects on GABA uptake or degradation. Pregabalin does not block sodium channels, is not active at opiate receptors, and does not alter cyclooxygenase enzyme activity. It is inactive at serotonin and dopamine receptors and does not inhibit dopamine, serotonin, or noradrenaline reuptake.
9	Warning	Black Box Warning	None.
10	Lactation	Use in Lactation	Advise nursing mothers that breastfeeding is not recommended during treatment with pregabalin extended-release tablets Tell your healthcare provider before taking pregabalin extended- release tablets if you are breastfeeding or plan to breastfeed. Pregabalin passes into your breast milk. It is not known if pregabalin extended-release tablets can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take pregabalin extended-release tablets.
11	Pregnancy	Use in Pregnancy	Pregabalin extended-release tablets may cause fetal harm. Advise pregnant patients to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry.
12	Precautions	Is there any interaction between medication and alcohol?	Do not drink alcohol while taking pregabalin extended-release tablets. Pregabalin extended-release tablets and alcohol can affect each other and increase side effects such as sleepiness and dizziness.
13	Interaction	Is there any interaction with food?	None.
14	Side effects	What are the common side effects?	The most common side effects of pregabalin extended-release tablets are dizziness, blurry vision, weight gain, sleepiness, fatigue (tiredness), swelling of hands and feet, dry mouth and nausea. *Please refer complete PI for more information*
15	Storage	What are the storage conditions?	Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F) in the original package. (See USP Controlled Room Temperature).
16	Dispensing	How to Dispense?	As prescribed by the Physician

17	Contraindication	What are the contraindications of (medication).	Pregabalin extended-release tablets are contraindicated in patients with known hypersensitivity to pregabalin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	82.5mg tablets: Brown colored, almond shaped, biconvex, film coated tablets debossed with “MP 12” on one side and plain on other side available in: Bottles of 30; NDC 72205-077-30. 165mg tablets: Pink colored, almond shaped, biconvex, film-coated tablets debossed with “MP 11” on one side and plain on other side: Bottles of 30; NDC 72205-078-30. 330mg tablets: Cream yellow colored, almond shaped, biconvex, film-coated tablets debossed with “MP 10” on one side and plain on other side available in: Bottles of 30; NDC 72205-079-30.
19	Ingredients	Active and Inactive Ingredients	**Active**: Pregabalin **Inactive**: carbopol, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, silicon dioxide. Film Coating contains polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide red (for 82.5 mg, 165 mg and 330 mg tablets), black iron oxide, (82.5 mg tablets) iron oxide yellow (for 330 mg tablets) and colorants as inactive ingredients.
20	Coating	What is the type of coating?	Film coated tablets
Allergens			
21	Ingredients	Is it Vegetarian?	Yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No
24	Ingredients	Does it contain Casein?	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
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?	No
35	Ingredients	Does it contain povidone?	No
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes, Pregabalin API Contains ISO propyl alcohol NMT 5000 PPM which is a very minute quantity
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	No
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