

Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	<p>Pregabalin capsule is indicated for:</p> <ul style="list-style-type: none"> -Neuropathic pain associated with diabetic peripheral neuropathy (DPN) -Postherpetic neuralgia (PHN) -Adjunctive therapy for the treatment of partial-onset seizures in patients 17 years of age and older. -Fibromyalgia -Neuropathic pain associated with spinal cord injury
2	Dosage	What is the recommended dosage?	<p>For adult indications, begin dosing at 150 mg/day.</p> <p>DPN Pain:</p> <ul style="list-style-type: none"> • Dosage regimen: 3 divided doses per day • Maximum Dose: 300 mg/day within 1 week. <p>PHN:</p> <ul style="list-style-type: none"> • Dosage regimen: 2 or 3 divided doses per day • Maximum dose: 300 mg/day within 1 week; Maximum dose of 600 mg/day. <p>Adjunctive Therapy for the treatment of Partial-Onset Seizures in Adult Patients 17 years of age and older:</p> <ul style="list-style-type: none"> • Dosing regimen: 2 or 3 divided doses per day • Maximum Dose: Maximum dose of 600 mg/day. <p>Fibromyalgia:</p> <ul style="list-style-type: none"> • Dosing Regimen: 2 divided doses per day • Maximum dose: 300 mg/day within 1 week; Maximum dose of 450 mg/day. <p>Neuropathic Pain Associated with Spinal Cord Injury:</p> <ul style="list-style-type: none"> • Dosing Regimen: 2 divided doses per day • Maximum dose: 300 mg/day within 1 week; Maximum dose of 600 mg/day. <p>Dose should be adjusted in patients with reduced renal function.</p>
3	Administration	How do I take?	Pregabalin capsules may be taken with or without food
4	Administration	What do I do if I miss a dose?	<p>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.</p> <p><i>Please contact your physician for further queries.</i></p>

5	Side effects	What are the most common and possible side effects?	<p>Dizziness, blurry vision, weight gain, sleepiness, trouble concentrating, swelling of hands and feet, dry mouth, Muscle problems, muscle pain, soreness, or weakness and feeling high.</p> <p><i>For more details please refer Full Prescribing Information</i></p>
6	Administration	Use in Pediatric Population	<p>Pediatric use information is approved for Pfizer's LYRICA (pregabalin) Capsules and Oral Solution products. However, due to Pfizer's marketing exclusivity rights, this drug product is not labeled with that pediatric information.</p>
7	Administration	Use in Geriatric Population	<p>No overall differences in safety and efficacy were observed between geriatric patients and younger patients.</p>
8	Mechanism	Mechanism of Action	<p>Pregabalin binds with high affinity to the alpha2-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. In animal models of nerve damage, pregabalin has been shown to reduce calcium dependent release of pro-nociceptive neurotransmitters in the spinal cord, possibly by disrupting alpha2-delta containing-calcium channel trafficking and/or reducing calcium currents. Evidence from other animal models of nerve damage and persistent pain suggest the anti-nociceptive activities of pregabalin may also be mediated through interactions with descending noradrenergic and serotonergic pathways originating from the brainstem that modulate pain transmission in the spinal cord.</p> <p>While pregabalin is a structural derivative of the inhibitory neurotransmitter gammaaminobutyric acid (GABA), it does not bind directly to GABA_A, GABA_B, or benzodiazepine receptors, does not augment GABA_A responses in cultured neurons, does not alter rat brain GABA concentration or have acute effects on GABA uptake or degradation. However, in cultured neurons prolonged application of pregabalin increases the density of GABA transporter protein and increases the rate of functional GABA transport. 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.</p>
9	Warning	Black Box Warning	<p>No Black Box warning</p>
10	Lactation	Use in Lactation	<p>Breastfeeding is not recommended during treatment with Pregabalin.</p>

11	Pregnancy	Use in Pregnancy	<p>May cause fetal harm. Advise pregnant women of the potential risk to a fetus.</p> <p>Pregnancy Exposure Registry- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to pregabalin during pregnancy. To provide information regarding the effects of in utero exposure to pregabalin, physicians are advised to recommend that pregnant patients taking pregabalin enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. This can be done by calling the toll free number 1-888-233-2334, and must be done by patients themselves.</p> <p>Information on the registry can also be found at the website http://www.aedpregnancyregistry.org/.</p>
12	Precautions	Is there any interaction between medication and alcohol.	Patients should avoid consuming alcohol while taking pregabalin, as pregabalin may potentiate the impairment of motor skills and sedating effects of alcohol.
13	Storage	What are the storage conditions?	Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).
14	Dispensing	How to Dispense?	As prescribed by the Physician
15	Contraindication	What are the contraindications of (medication)?	Known hypersensitivity to pregabalin or any of its components.
Pharmaceutical Particulars			
16	Pharmaceutical Form	How Supplied	<p>25 mg capsules: White to off White color granular powder filled in Size “4” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “25” with black ink available in: Bottles of 90: NDC 72205-011-90; Bottles of 1000: NDC 72205-011-99; Unit-Dose Blister packages of 100: NDC 72205-011-06</p> <p>50 mg capsules: White to off White color granular powder filled in Size “4” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “50” with black ink available in: Bottles of 90: NDC 72205-012-90; Bottles of 1000: NDC 72205-012-99; Unit-Dose Blister packages of 100: NDC 72205-012-06</p> <p>75 mg capsules: White to off White color granular powder filled in Size “4” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “75” with black ink available in: Bottles of 90: NDC 72205-013-90; Bottles of 1000: NDC 72205-013-99; Unit-Dose Blister packages of 100: NDC 72205-013-06</p> <p>100 mg capsules: White to off White color granular powder filled in Size “3” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “100” with black ink available in: Bottles of 90: NDC 72205-014-90; Bottles of 1000: NDC</p>

			<p>72205-014-99; Unit-Dose Blister packages of 100: NDC 72205-014-06</p> <p>150 mg capsules: White to off White color granular powder filled in Size “2” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “150” with black ink available in: Bottles of 90: NDC 72205-015-90; Bottles of 500: NDC 72205-015-05; Unit-Dose Blister packages of 100: NDC 72205-015-06</p> <p>200 mg capsules: White to off White color granular powder filled in Size “1” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “200” with black ink available in: Bottles of 90: NDC 72205-016-90; Bottles of 1000: NDC 72205-016-99; Unit-Dose Blister packages of 100: NDC 72205-016-06</p> <p>225 mg capsules: White to off White color granular powder filled in Size “1” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “225” with black ink available in: Bottles of 90: NDC 72205-017-90; Bottles of 1000: NDC 72205-017-99; Unit-Dose Blister packages of 100: NDC 72205-017-06</p> <p>300 mg capsules: White to off White color granular powder filled in Size “0” hard gelatin capsules with White Opaque body imprinted “PGBN” and light blue Opaque cap imprinted “300” with black ink available in: Bottles of 90: NDC 72205-018-90; Bottles of 500: NDC 72205-018-05; Unit-Dose Blister packages of 100: NDC 72205-018-06.</p>
17	Ingredients	Active and Inactive	<p>Active ingredient: Pregabalin Inactive ingredients: Pregabalin capsules: Mannitol, talc The capsule shells contain FD&C Blue No. 2, gelatin, titanium dioxide, sodium lauryl sulphate and is imprinted with black ink. Black imprinting ink contains shellac, propylene glycol, black iron oxide and potassium hydroxide.</p>
Allergens			
18	Ingredients	Does it contain Gluten?	No
19	Ingredients	Does it contain alcohol?	No
20	Ingredients	Does it contain dyes?	No
21	Ingredients	Does it contain Lactose?	No
22	Ingredients	Does it contain Nuts?	No
23	Ingredients	Does it contain Preservatives?	No
24	Ingredients	Does it contain Soy products?	No
25	Ingredients	Does it contain peanut?	No

26	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
27	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
28	Miscellaneous	May I know about return, refunds and reimbursement ?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
29	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
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