

LOSARTAN POTASSIUM TABLETS USP 25, 50, 100 mg

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1.	Use/Indication	What is the product indicated for?	<ul style="list-style-type: none"> <li>• <i>Hypertension Treatment:</i> Lowers blood pressure in adults and children over 6, reducing the risk of cardiovascular events like strokes and heart attacks.</li> <li>• <i>Stroke Risk Reduction:</i> Reduces stroke risk in hypertensive patients with left ventricular hypertrophy, though not applicable to Black patients.</li> <li>• <i>Diabetic Nephropathy:</i> Treats nephropathy in type 2 diabetes patients with elevated creatinine and proteinuria, and a history of hypertension.</li> </ul>
2.	Dosage	What is the recommended dosage?	<p><b>Hypertension:</b></p> <ul style="list-style-type: none"> <li>• <b>Usual Adult Dose:</b> 50 mg once daily.</li> <li>• <b>Usual Pediatric Starting Dose:</b> 0.7 mg per kg once daily, up to a maximum of 50 mg.</li> </ul> <p><b>Hypertensive Patients with Left Ventricular Hypertrophy:</b></p> <ul style="list-style-type: none"> <li>• <b>Usual Starting Dose:</b> 50 mg once daily.</li> <li>• If additional blood pressure control is needed, consider adding <b>hydrochlorothiazide 12.5 mg</b> and/or increasing the losartan potassium dose to <b>100 mg daily</b>. If further response is required, increase hydrochlorothiazide to <b>25 mg daily</b>.</li> </ul> <p><b>Nephropathy in Type 2 Diabetic Patients:</b></p> <ul style="list-style-type: none"> <li>• <b>Usual Dose:</b> 50 mg once daily.</li> <li>• If further blood pressure control is needed, increase the dose to <b>100 mg once daily</b>.</li> </ul>
3.	Administration	How do I take it?	<ul style="list-style-type: none"> <li>✓ Take losartan potassium tablets exactly as prescribed by your doctor. Your doctor may change your dose if needed.</li> <li>✓ Losartan potassium tablets can be taken with or without food.</li> <li>✓ If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time.</li> <li>✓ If you take too much losartan potassium tablets, call</li> </ul>

			your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.
4.	Administration	Use in Pediatric Population	Losartan Potassium is not recommended for use in pediatric patients under 6 years of age or in those with a glomerular filtration rate (GFR) of less than 30 mL/min/1.73 m <sup>2</sup> .
5.	Administration	Use in Geriatric Population	No significant differences in effectiveness or safety were observed between older and younger patients, although increased sensitivity in some older individuals cannot be ruled out.
6.	Mechanism	Mechanism of Action	Angiotensin II, a potent vasoconstrictor and key hormone in the renin-angiotensin system, plays a critical role in hypertension and stimulates aldosterone release. Losartan and its active metabolite block the effects of angiotensin II by selectively binding to the AT receptor in tissues such as vascular smooth muscle and the adrenal gland. Losartan does not have partial agonist activity at the AT receptor and has a 1000-fold greater affinity for the AT receptor than the AT receptor. The active metabolite is 10 to 40 times more potent and acts as a non-competitive inhibitor. Neither losartan nor its metabolite inhibits ACE or affects other cardiovascular hormone receptors or ion channels.
7.	Warning	Black Box Warning	If pregnancy is detected, discontinue losartan potassium immediately. Drugs that directly affect the renin-angiotensin system can cause harm or death to the developing fetus.
8.	Lactation	Use in Lactation	It is unknown whether losartan potassium passes into breast milk. You should decide between taking losartan potassium or breastfeeding, but not both.
9.	Pregnancy	Use in Pregnancy	<ul style="list-style-type: none"> <li>▪ Losartan potassium tablets can cause harm or death to an unborn baby.</li> <li>▪ Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant.</li> <li>▪ If you get pregnant while taking losartan potassium tablets, tell your doctor right away.</li> </ul>
10.	Interaction	Is there any interaction with other medication?	<ul style="list-style-type: none"> <li>• Agents Increasing Serum Potassium: Risk of hyperkalemia.</li> <li>• Lithium: Risk of lithium toxicity.</li> <li>• NSAIDs: Increased risk of renal impairment and reduced effectiveness of diuretics, natriuretics, and antihypertensive treatments.</li> <li>• Dual Inhibition of the Renin-Angiotensin System: Increased risk of renal impairment, hypotension, syncope, and hyperkalemia.</li> </ul>
11.	Storage	What are the storage conditions?	<ul style="list-style-type: none"> <li>• Store losartan potassium tablets at 59°F to 86°F (15°C to 30°C).</li> <li>• Keep losartan potassium tablets in a tightly closed container that protects the medicine from light.</li> <li>• Keep losartan potassium tablets and all medicines out of the reach of children.</li> </ul>
12.	Dispensing	How to Dispense?	As prescribed by the Physician
13.	Contraindication	What are the contraindications of	<ul style="list-style-type: none"> <li>▪ <b>Hypersensitivity</b> to any component.</li> <li>▪ <b>Coadministration with aliskiren</b> in patients with</li> </ul>

		(medication).	diabetes.
<b>Pharmaceutical Particulars</b>			
14.	Pharmaceutical Form	How is it supplied?	<p><b>Losartan Potassium Tablets, USP</b> are available as follows:</p> <ul style="list-style-type: none"> <li>• <b>25 mg tablets:</b> White, oval-shaped, biconvex, film-coated tablets, debossed with “ML” on one side and “14” on the other side. <ul style="list-style-type: none"> <li>• Bottles of 90, NDC 72205-141-90</li> <li>• Bottles of 1000, NDC 72205-141-99</li> </ul> </li> <li>• <b>50 mg tablets:</b> White, oval-shaped, biconvex, film-coated tablets, debossed with “M” and “L” separated by a score line on one side and “15” on the other side. <ul style="list-style-type: none"> <li>• Bottles of 30, NDC 72205-142-30</li> <li>• Bottles of 90, NDC 72205-142-90</li> <li>• Bottles of 1000, NDC 72205-142-99</li> </ul> </li> <li>• <b>100 mg tablets:</b> White, teardrop-shaped, biconvex, film-coated tablets, debossed with “ML” on one side and “16” on the other side. <ul style="list-style-type: none"> <li>• Bottles of 30, NDC 72205-143-30</li> <li>• Bottles of 90, NDC 72205-143-90</li> <li>• Bottles of 1000, NDC 72205-143-99</li> </ul> </li> </ul>
15.	Ingredients	Active and Inactive Ingredients	<p><b>Active:</b> Losartan potassium</p> <p><b>Inactive:</b> lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, hydroxypropyl cellulose, hypromellose, and titanium dioxide.</p>
<b>Allergens</b>			
16.	Ingredients	Is it Vegetarian?	No
17.	Ingredients	Does it contain Gluten?	No
18.	Ingredients	Does it contain Dairy Products?	Yes
19.	Ingredients	Does it contain Casein	No
20.	Ingredients	Does it contain Whey?	No
21.	Ingredients	Does it contain corn?	Yes
22.	Ingredients	Does it contain rye?	No
23.	Ingredients	Does it contain sugar?	No

24.	Ingredients	Does it contain Oats?	No
25.	Ingredients	Does it contain wheat?	No
26.	Ingredients	Does it contain spelt?	No
27.	Ingredients	Does it contain barley?	No
28.	Ingredients	Does it contain rennet?	No
29.	Ingredients	Does it contain starch?	Yes
30.	Ingredients	Does it contain Iodine?	No
31.	Ingredients	Does it contain latex?	No
32.	Ingredients	Does it contain alcohol?	Yes; (API contains solvents within the limits as per ICH)
33.	Ingredients	Does it contain dyes?	No
34.	Ingredients	Does it contain flavor?	No
35.	Ingredients	Does it contain Lactose?	Yes (Lactose used as diluant in the FP products and sourced from Cow's milk)
36.	Ingredients	Does it contain Nuts?	No
37.	Ingredients	Does it contain Preservatives?	No
38.	Ingredients	Does it contain Soy products?	No
39.	Ingredients	Does it contain peanut?	No
40.	Ingredients	Does it contain nickel?	No
<b>Miscellaneous</b>			
41.	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.
42.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
43.	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.
44.	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.
45.	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.
46.	Miscellaneous	Manufacturer and Distributor	<b>MSN Pharmaceuticals Inc</b> <b>MSN Laboratories Private Limited,</b>

			<p><b>Unit – II, Formulations Division, Nandigama</b></p> <p><b>Distributed by:</b> <b>Novadoz Pharmaceuticals LLC</b> <b>Piscataway, NJ 08854-3714</b></p>
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