

NEBIVOLOL TABLETS, 2.5 mg, 5 mg, 10 mg, 20 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1.	1 Use/Indication	What is the product indicated for?	Nebivolol tablets are a beta-adrenergic blocking agent indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions
2.	Dosage	What is the recommended dosage?	<p>▼ Hypertension: Most patients start at 5 mg once daily. Dose can be increased at 2-week intervals up to 40 mg.</p>
3.	3 Administration	How do I take it?	<ul style="list-style-type: none"> ➤ Take nebivolol tablets every day exactly as your doctor tells you. Your doctor will tell you how much nebivolol tablets to take and how often. Your doctor may start with a low dose and raise it over time. ➤ Do not stop taking nebivolol tablets or change your dose without talking with your doctor. ➤ Take nebivolol tablets with or without food. ➤ If you miss a dose, take your dose as soon as you remember, unless it is close to the time to take your next dose. Do not take 2 doses at the same time. Take your next dose at the usual time. <p>If you take too much nebivolol, call your doctor or poison control center right away.</p> <ul style="list-style-type: none"> ➤ Do not suddenly stop taking nebivolol tablets. You could have chest pain or a heart attack. If your doctor decides to stop nebivolol tablets, your doctor may slowly lower your dose over time before stopping it completely.
4.	Administration	Use in Pediatric Population	Safety and effectiveness in pediatric patients have not been established.
5.	Administration	Use in Geriatric Population	<ul style="list-style-type: none"> • No overall differences in efficacy or in the incidence of adverse events were observed between older and younger patients.
6.	Mechanism	Mechanism of Action	The mechanism of action of the antihypertensive response of nebivolol has not been definitively established. Possible factors that may be involved include: Decreased heart rate, decreased myocardial contractility, diminution of tonic sympathetic outflow to the periphery from cerebral vasomotor centers, suppression of renin activity and vasodilation and decreased peripheral vascular resistance.

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7.	Warning	Warning	<p>Acute exacerbation of coronary artery disease upon cessation of therapy: Do not abruptly discontinue.</p> <p>Diabetes: May mask symptoms of hypoglycemia and alter glucose levels; monitor</p>
8.	Lactation	Use in Lactation	Breastfeeding is not recommended.
9.	Pregnancy	Use in Pregnancy	<ul style="list-style-type: none"> ➤ Are pregnant or trying to become pregnant. It is not known if nebivolol tablets are safe for your unborn baby. Talk with your doctor about the best way to treat high blood pressure while you are pregnant.
10.		Who should not take	<p>Do not take nebivolol tablets if you:</p> <ul style="list-style-type: none"> • Have heart failure and are in the ICU or need medicines to keep up your blood circulation • Have a slow heartbeat or your heart skips beats (irregular heartbeat) • Have severe liver damage • Are allergic to any ingredient in nebivolol tablets. The active ingredient is nebivolol. See the end of this leaflet for a list of ingredients.
11.	Precautions	Using alcohol	No
12.	Interaction	Is there any interaction with other medication?	<ul style="list-style-type: none"> ➤ CYP2D6 enzyme inhibitors may increase nebivolol levels. ➤ Reserpine or clonidine may produce excessive reduction of sympathetic activity. ➤ Both digitalis glycosides and β-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia. ➤ Verapamil- or diltiazem-type calcium channel blockers may cause excessive reductions in heart rate, blood pressure, and cardiac contractility.
13.	Precautions	After taking food	<ul style="list-style-type: none"> • Can be taken with and without food.
14.	Storage	What are the storage conditions?	<ul style="list-style-type: none"> • Store at 20° to 25°C (68° to 77°F) • Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
15.	Dispensing	How to Dispense?	As prescribed by the Physician
16.	Contraindication	What are the contraindications of (medication).	<ul style="list-style-type: none"> • Severe bradycardia • Heart block greater than first degree • Patients with cardiogenic shock • Decompensated cardiac failure • Sick sinus syndrome (unless a permanent pacemaker is in place) • Patients with severe hepatic impairment (Child-

			<p>Pugh >B)</p> <ul style="list-style-type: none"> Hypersensitive to any component of this product
Pharmaceutical Particulars			
17.	Pharmaceutical Form	How is it supplied?	<p>1. <i>Nebivolol tablets 2.5 mg:</i></p> <ul style="list-style-type: none"> Blue colored, triangular shaped, unscored tablets Debossed with “M” on one side and “N6” on other side. Supplied as: <ul style="list-style-type: none"> NDC 72205-150-30: Bottle of 30 NDC 72205-150-90: Bottle of 90 NDC 72205-150-91: Bottle of 100 NDC 72205-150-99: 10 x 10 Unit Dose <p>2. <i>Nebivolol tablets 5 mg:</i></p> <ul style="list-style-type: none"> Beige colored, triangular shaped, unscored tablets Debossed with “M” on one side and “N7” on other side. Supplied as: <ul style="list-style-type: none"> NDC 72205-151-30: Bottle of 30 NDC 72205-151-90: Bottle of 90 NDC 72205-151-91: Bottle of 100 NDC 72205-151-99: 10 x 10 Unit Dose <p>3. <i>Nebivolol tablets 10 mg:</i></p> <ul style="list-style-type: none"> Pink colored, triangular shaped, unscored tablets Debossed with “M” on one side and “N8” on other side. Supplied as: <ul style="list-style-type: none"> NDC 72205-152-30: Bottle of 30 NDC 72205-152-90: Bottle of 90 NDC 72205-152-91: Bottle of 100 NDC 72205-152-99: 10 x 10 Unit Dose <p>4. <i>Nebivolol tablets 20 mg:</i></p> <ul style="list-style-type: none"> Blue colored, triangular shaped, unscored tablets debossed with “M” on one side and “N9” on other side. Supplied as: <ul style="list-style-type: none"> NDC 72205-153-30: Bottle of 30 NDC 72205-153-90: Bottle of 90 NDC 72205-153-91: Bottle of 100 NDC 72205-153-99: 10 x 10 Unit Dose
18.	Ingredients	Active and Inactive Ingredients	<p>Active: Nebivolol</p> <p>Inactive: Croscarmellose sodium, colloidal silicon dioxide, hydroxypropyl methylcellulose, lactose monohydrate,</p>

			microcrystalline cellulose, magnesium stearate, pregelatinized starch, polysorbate 80, FD&C blue No. 2 (2.5 mg and 20 mg), FD&C yellow No. 6 (5 mg), and FD&C red No. 40 (10 mg).
Allergens			
19.	Ingredients	Is it Vegetarian?	NO
20.	Ingredients	Does it contain Gluten?	NO
21.	Ingredients	Does it contain Dairy Products?	Lactose used as diluant in the FP products and sourced from Cow's milk
22.	Ingredients	Does it contain Casein	NO
23.	Ingredients	Does it contain Whey?	NO
24.	Ingredients	Does it contain corn?	Pregelatinized Starch Excipient contains Starch
25.	Ingredients	Does it contain rye?	NO
26.	Ingredients	Does it contain sugar?	NO
27.	Ingredients	Does it contain Oats?	NO
28.	Ingredients	Does it contain wheat?	NO
29.	Ingredients	Does it contain spelt?	NO
30.	Ingredients	Does it contain barley?	NO
31.	Ingredients	Does it contain rennet?	NO
32.	Ingredients	Does it contain starch?	YES
33.	Ingredients	Does it contain Iodine?	NO
34.	Ingredients	Does it contain latex?	NO
35.	Ingredients	Does it contain alcohol?	API contains solvents within the limits as per ICH
36.	Ingredients	Does it contain dyes?	Coating materials contains Azo dyes
37.	Ingredients	Does it contain flavor?	NO
38.	Ingredients	Does it contain Lactose?	Lactose produced from milk, that has been sourced from healthy cows.
39.	Ingredients	Does it contain Nuts?	NO
40.	Ingredients	Does it contain Preservatives?	NO
41.	Ingredients	Does it contain Soy products?	NO
42.	Ingredients	Does it contain peanut?	NO
43.	Ingredients	Does it contain nickel?	NO
Miscellaneous			
44.	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.
45.	Miscellaneous	May I know about return,	Contact Novadoz Pharmaceuticals Customer Service directly at

		refunds and reimbursement?	908-360-1500
46.	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.
47.	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 .
48.	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.
49.	Miscellaneous	Manufacturer and Distributor	<p>Manufactured by: MSN Laboratories Private Limited, Unit – II, Formulations Division, Nandigama</p> <p>Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854 -374 Issued on: 08/2023</p>