

## Moxifloxacin Hydrochloride USP Tablets 400 mg

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1.	Use/Indication	What is the product indicated for?	<p>Moxifloxacin tablets are a fluoroquinolone antibiotic indicated for treating infections in adults 18 and older caused by susceptible bacteria, including:</p> <ul style="list-style-type: none"> <li>• Community-Acquired Pneumonia</li> <li>• Uncomplicated and Complicated Skin Infections</li> <li>• Complicated Intra-Abdominal Infections</li> <li>• Plague</li> <li>• Acute Bacterial Sinusitis</li> <li>• Acute Bacterial Exacerbation of Chronic Bronchitis</li> </ul> <p>To reduce the risk of drug-resistant bacteria, moxifloxacin should only be used for infections proven or strongly suspected to be caused by susceptible bacteria.</p>
2.	Dosage	What is the recommended dosage?	<ul style="list-style-type: none"> <li>▪ <b>Community-Acquired Pneumonia:</b> 400 mg once daily, for 7 to 14 days</li> <li>▪ <b>Uncomplicated Skin and Skin Structure Infections (SSSI):</b> 400 mg once daily, for 7 days</li> <li>▪ <b>Complicated SSSI:</b> 400 mg once daily, for 7 to 21 days</li> <li>▪ <b>Complicated Intra-Abdominal Infections:</b> 400 mg once daily, for 5 to 14 days</li> <li>▪ <b>Plague:</b> 400 mg once daily, for 10 to 14 days</li> <li>▪ <b>Acute Bacterial Sinusitis:</b> 400 mg once daily, for 10 days</li> <li>▪ <b>Acute Bacterial Exacerbation of Chronic Bronchitis:</b> 400 mg once daily, for 5 days.</li> </ul>
3.	Administration	How do I take it?	<ul style="list-style-type: none"> <li>✓ Take <b>1 tablet</b> of moxifloxacin <b>once a day</b> exactly as prescribed by your healthcare provider.</li> <li>✓ Take the tablet at about the <b>same time each day</b>.</li> <li>✓ Moxifloxacin can be taken with or without food.</li> <li>✓ If you miss a dose: <ul style="list-style-type: none"> <li>• If it's <b>8 hours or more</b> until your next dose, take the missed dose right away, then continue with your regular schedule.</li> <li>• If it's <b>less than 8 hours</b> until your next dose, skip the missed dose and take the next one at your usual time.</li> </ul> </li> <li>✓ <b>Do not take two doses</b> to make up for a missed dose. If you're unsure, consult your doctor or pharmacist.</li> <li>✓ Drink plenty of fluids while taking moxifloxacin</li> </ul>

			<p>tablets.</p> <ul style="list-style-type: none"> <li>✓ <b>Do not skip doses</b> or stop taking moxifloxacin even if you feel better, unless: <ul style="list-style-type: none"> <li>• You experience tendon issues (refer to "What is the most important information I should know about moxifloxacin tablets?")</li> <li>• You have nerve problems or central nervous system effects (refer to the same section)</li> <li>• You experience a severe allergic reaction (refer to "What are the possible side effects of moxifloxacin tablets?")</li> <li>• Your healthcare provider advises you to stop.</li> </ul> </li> </ul> <p><i>Completing your full course of treatment ensures that all bacteria are eradicated and reduces the risk of antibiotic resistance. If you accidentally take too much, contact your healthcare provider or seek immediate medical help.</i></p>
4.	Administration	Use in Pediatric Population	<ul style="list-style-type: none"> <li>▪ Effectiveness in pediatric patients and adolescents less than 18 years of age has not been established.</li> <li>▪ It is not known whether moxifloxacin tablets are safe or effective in individuals under 18 years of age.</li> </ul>
5.	Administration	Use in Geriatric Population	Increased risk for severe tendon disorders further increased by concomitant corticosteroid therapy and increased risk of prolongation of the QT interval.
6.	Mechanism	Mechanism of Action	Moxifloxacin hydrochloride is a member of the fluoroquinolone class of antibacterial agents.
7.	Warning	Black Box Warning	<p>Fluoroquinolones, including moxifloxacin hydrochloride, have been associated with disabling and potentially irreversible serious adverse reactions, which may occur together, such as:</p> <ul style="list-style-type: none"> <li>• Tendinitis and tendon rupture</li> <li>• Peripheral neuropathy</li> <li>• Central nervous system effects</li> </ul> <p>If any of these reactions occur, <b>discontinue moxifloxacin hydrochloride immediately</b> and avoid further use of fluoroquinolones in affected patients.</p> <p>Moxifloxacin hydrochloride may also worsen muscle weakness in patients with myasthenia gravis. It should be avoided in individuals with a known history of this condition.</p> <p>Due to the risk of serious adverse reactions, <b>reserve moxifloxacin hydrochloride</b> for patients who have no alternative treatment options for the following conditions:</p> <ul style="list-style-type: none"> <li>• Acute bacterial sinusitis</li> <li>• Acute bacterial exacerbation of chronic bronchitis.</li> </ul>

8.	Lactation	Use in Lactation	If you are breastfeeding or plan to breastfeed, it is not known whether moxifloxacin hydrochloride passes into breast milk. You and your healthcare provider should discuss whether to take moxifloxacin tablets or breastfeed.
9.	Pregnancy	Use in Pregnancy	<ul style="list-style-type: none"> <li>▪ If you are pregnant or planning to become pregnant, it is not known whether moxifloxacin tablets could harm your unborn baby.</li> <li>▪ Based on animal data may cause fetal harm.</li> </ul>
10.	Interaction	Is there any interaction with other medication?	<p><b><i>Drug Interactions with Moxifloxacin Tablets:</i></b></p> <ul style="list-style-type: none"> <li>• <b><i>Multivalent Cation-Containing Products (e.g., antacids, sucralfate, multivitamins):</i></b> These can decrease the absorption of moxifloxacin. Take moxifloxacin at least 4 hours before or 8 hours after taking these products.</li> <li>• <b><i>Warfarin:</i></b> Moxifloxacin may enhance the anticoagulant effect of warfarin. Monitor prothrombin time/INR and watch for signs of bleeding.</li> <li>• <b><i>Class IA and Class III Antiarrhythmics:</i></b> The proarrhythmic effect may be enhanced. Avoid concomitant use.</li> <li>• <b><i>Antidiabetic Agents:</i></b> Carefully monitor blood glucose levels.</li> </ul>
11.	Precautions	After taking food	<ul style="list-style-type: none"> <li>• Inform patients that moxifloxacin tablets may be taken with or without food. Advise patients drink fluids liberally.</li> <li>• Inform patients that moxifloxacin tablets should be taken at least 4 hours before or 8 hours after multivitamins (containing iron or zinc), antacids (containing magnesium or aluminum), sucralfate, or didanosine buffered tablets for oral suspension or the pediatric powder for oral solution.</li> <li>• Advise patients that if a dose is missed, it should be taken anytime but not later than 8 hours prior to the next scheduled dose. If less than 8 hours remain before the next dose, the missed dose should not be taken and treatment should be continued as prescribed with the next scheduled dose. Double doses should not be taken to compensate for a missed dose.</li> </ul>
12.	Storage	What are the storage conditions?	<ul style="list-style-type: none"> <li>▪ Store moxifloxacin tablets at room temperature between 68°F to 77°F (20°C to 25°C).</li> <li>▪ Keep moxifloxacin tablets away from moisture (humidity).</li> </ul>
13.	Dispensing	How to Dispense?	As prescribed by the Physician
14.	Contraindication	What are the contraindications of (medication).	Moxifloxacin hydrochloride is contraindicated in persons with a history of hypersensitivity to moxifloxacin or any member of the quinolone class of antibacterials.
<b>Pharmaceutical Particulars</b>			
15.	Pharmaceutical Form	How is it supplied?	<b>Moxifloxacin Tablets, USP</b> are available as dull red-coloured, caplet-shaped, film-coated tablets, each containing <b>400 mg of moxifloxacin</b> . The tablet is debossed with "M" on one side and

			"400" on the other side.  <b>Package NDC Codes:</b>  <ul style="list-style-type: none"> <li>• <b>Bottles of 30 tablets:</b> NDC 69539-006-30</li> <li>• <b>Bottles of 500 tablets:</b> NDC 69539-006-05</li> <li>• <b>Cartons of 50 (5 x 10) unit-dose tablets:</b> NDC 69539-006-31.</li> </ul>
16.	Ingredients	Active and Inactive Ingredients	<b>Active:</b> Moxifloxacin hydrochloride  <b>Inactive:</b> actose monohydrate, povidone, lactose anhydrous, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol and iron oxide red.
<b>Allergens</b>			
17.	Ingredients	Is it Vegetarian?	No
18.	Ingredients	Does it contain Gluten?	No
19.	Ingredients	Does it contain Dairy Products?	YES (Lactose produced from milk, that has been sourced from healthy cows)
20.	Ingredients	Does it contain Casein	No
21.	Ingredients	Does it contain Whey?	No
22.	Ingredients	Does it contain corn?	No
23.	Ingredients	Does it contain rye?	No
24.	Ingredients	Does it contain sugar?	No
25.	Ingredients	Does it contain Oats?	No
26.	Ingredients	Does it contain wheat?	No
27.	Ingredients	Does it contain spelt?	No
28.	Ingredients	Does it contain barley?	No
29.	Ingredients	Does it contain rennet?	No
30.	Ingredients	Does it contain starch?	No
31.	Ingredients	Does it contain Iodine?	No
32.	Ingredients	Does it contain latex?	No
33.	Ingredients	Does it contain alcohol?	Yes (API contains solvents within the limits as per ICH)
34.	Ingredients	Does it contain dyes?	No
35.	Ingredients	Does it contain flavor?	No
36.	Ingredients	Does it contain Lactose?	YES (Lactose produced from milk, that has been sourced from healthy cows)
37.	Ingredients	Does it contain Nuts?	No

38.	Ingredients	Does it contain Preservatives?	No
39.	Ingredients	Does it contain Soy products?	No
40.	Ingredients	Does it contain peanut?	No
41.	Ingredients	Does it contain nickel?	No
<b>Miscellaneous</b>			
42.	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.
43.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
44.	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.
45.	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 <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a> .
46.	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.
47.	Miscellaneous	Manufacturer and Distributor	<b>Manufactured by:</b> <b>MSN laboratories pvt Ltd,</b> <b>Formulation divisions unit -II nandigama. INDIA</b>  <b>Distributed by:</b> <b>Novadoz Pharmaceuticals LLC</b> <b>Piscataway, NJ 08854-3714</b>