

Moxifloxacin Hydrochloride Tablets, 400 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	<p>Moxifloxacin tablets are fluoroquinolone antibacterial indicated for treating infections in adults 18 years of age and older caused by designated susceptible bacteria, in the conditions listed below:</p> <ul style="list-style-type: none"> • Community Acquired Pneumonia • Skin and Skin Structure Infections: Uncomplicated and Complicated • Complicated Intra-Abdominal Infections • Plague • Acute Bacterial Sinusitis • Acute Bacterial Exacerbation of Chronic Bronchitis <p>To reduce the development of drug-resistant bacteria and maintain the effectiveness of moxifloxacin hydrochloride and other antibacterial drugs. Moxifloxacin hydrochloride should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.</p>
2	Dosage	What is the recommended dosage?	<p>The dose of moxifloxacin tablets is 400 mg (orally) once every 24 hours.</p> <p>The duration of therapy depends on the type of infection.</p> <ul style="list-style-type: none"> • Community Acquired Pneumonia: 7 to 14 days • Uncomplicated Skin and Skin Structure Infections (SSSI): 7 days • Complicated SSSI: 7 to 21 days • Complicated Intra-Abdominal Infections: 5 to 14 days • Plague: 10 to 14 days • Acute Bacterial Exacerbation of Chronic Bronchitis (ABECB): 5 days • Acute Bacterial Sinusitis (ABS): 10 days
3	Administration	How should I take moxifloxacin tablets?	<p>Take moxifloxacin tablets once a day exactly as prescribed by your healthcare provider.</p> <ul style="list-style-type: none"> • Take moxifloxacin tablets at about the same time each day. • Moxifloxacin tablets should be swallowed. • Drink plenty of fluids while taking moxifloxacin tablets.
4	Administration	Can moxifloxacin be taken with food?	Moxifloxacin tablets can be taken with or without food.
5	Administration	Important instruction for administration	Administer moxifloxacin tablets at least 4 hours before or 8 hours after products containing magnesium, aluminum, iron or zinc, including antacids, sucralfate, multivitamins and didanosine buffered tablets for oral suspension or the pediatric powder for oral solution.
6	Administration	What do I do if I miss a dose?	If you miss a dose of moxifloxacin tablets, take it as soon as you remember. Do not take more than 1 dose of moxifloxacin tablets in one day.
7	Administration	Use in Pediatric Population	Effectiveness in pediatric patients and adolescents less than 18 years of age has not been established.

8	Administration	Use in Geriatric Population	Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as moxifloxacin hydrochloride. This risk is further increased in patients receiving concomitant corticosteroid therapy. Patients are advised to discontinue moxifloxacin hydrochloride and contact their healthcare provider if any symptoms of tendinitis or tendon rupture occur.
9	Formulation	Can tablet be crushed?	Not recommended
10	Side effects	What are the common side effects of moxifloxacin tablets?	Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion).
11	Mechanism	Mechanism of Action	Moxifloxacin hydrochloride is a member of the fluoroquinolone class of antibacterial agents. The bactericidal action of moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV required for bacterial DNA replication, transcription, repair, and recombination.
12	Warning	Black Box Warning	Serious adverse reactions including tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects and exacerbation of myasthenia gravis.
13	Lactation	Use in Lactation	It is not known if moxifloxacin is present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for moxifloxacin and any potential adverse effects on the breastfed child from moxifloxacin or from the underlying maternal condition.
14	Pregnancy	Use in Pregnancy	There are no available human data establishing a drug associated risk with the use of moxifloxacin. Based on animal studies with moxifloxacin may cause fetal harm.
15	Precautions	Is there any interaction between medication and alcohol.	Not Available.
16	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.
17	Storage	What are the storage conditions?	Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F). Avoid high humidity.
18	Dispensing	How to Dispense?	As prescribed by the Physician
Pharmaceutical Particulars			
19	Pharmaceutical Form	How Supplied	Moxifloxacin Tablets, USP are available as dull red colored, caplet shaped, film-coated tablets containing 400 mg moxifloxacin. The tablet is debossed with "M" on one side and "400" on other side. Package Bottles of 30 Bottles of 500 Cartons of 50 (5 x 10) Unit-dose Tablets NDC Code 72205-001-30 72205-001-05 72205-001-31
20	Ingredients	Active and Inactive	Active Ingredient: Moxifloxacin hydrochloride USP Inactive Ingredients: Lactose Monohydrate, Povidone, Lactose Anhydrous, Croscarmellose sodium, Colloidal silicon dioxide, Magnesium stearate, hypromellose, Titanium dioxide, Polyethylene glycol and iron oxide red.
21	Coating	What is the type of coating?	No

Allergens			
22	Ingredients	Is it Vegetarian?	Yes
23	Ingredients	Does it contain Gluten?	Yes
24	Ingredients	Does the product contain povidone?	Yes
25	Ingredients	Does it contain alcohol?	Yes
26	Ingredients	Does it contain dyes?	Yes
27	Ingredients	Does it contain Lactose?	No
28	Ingredients	Does it contain Nuts?	No
29	Ingredients	Does it contain Preservatives?	No
30	Ingredients	Does it contain Soy products?	Film-coated
31	Ingredients	Does it contain peanut?	No
32	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
33	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
34	Miscellaneous	May I know about return, refunds and reimbursement ?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
35	Miscellaneous	Do you have any patient's assistance program ?	As a generics medications manufacturer, MSN Laboratories Private Limited, currently does not offer a patient assistance program.
36	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 .
37	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
38	Miscellaneous	Where are your drugs manufactured?	<p>Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA</p> <p>Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714</p>