# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

## Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

**Version 2021** | **Introduction Type:** New Item | Final Version | **Date:** 7/23/2024

### PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| **Company Name:** | Novadoz Pharmaceuticals, LLC | **Application:** | ANDA |
| **Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** | 208682 | | |
| **Medical Device Class, if applicable:** | | | |
| **DUNS:** | 081109687 | | |
| **Proprietary Name (If Applicable) and Established Name:** | Moxifloxacin Tablets, USP 400 mg 30's | | |
| **Selling Unit NDC:** | 72205-001-30 | **Unit of Use NDC:** | **UPC:** 372205001305 |
| **UDI** | | **CVX Code:** | **MVX Code:** |
| **Description:** | Dull red colored,Caplet Shaped, Film Coated Tablets, debossed with 'M' on one side and '400' on other side. | | |
| **Active Ingredient(s):** | Moxifloxacin | | |
| **URL for Additional Product Information:** | | | |
| **Address:** | 20 Duke Road | **Address 2:** | Suite A |
| **City:** | Piscataway | **State:** NJ | **Zip:** 08854 |
| **Key Contact:** | | **Email:** | sales@novadozpharma.com |
| **Phone Number:** | 908-360-1500 | **Fax:** | 732-902-2113 |
| **Product Therapeutic Classification:** | | | |

### ADDITIONAL PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| **The product is?** | | **Is the Product…** | Direct-Ship Only |
| **a legend device?** | No | **Is the Product…** | Neither |
| **if yes, enter class #** | | **Orphan Drug Status** | |
| **a product kit?** | No | | |
| **if yes, list NDCs of component parts** | | **FDA Approval Status** | |
| **reverse numbered?** | | | |
| **co-licensed?** | | **Allergens Present** | |
| **latex-free?** | Yes | | |
| **preservative-free?** | Yes | | |
| **correctional institution block?** | | | |
| **opioid?** | | | |
| **Cannabinoid?** | | Country of Origin | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | | | |
| If Unit Dose, indicate NDC here: | 72205-001-30 | Is this product covered under the Trade Agreements Act (TAA)? | No |

### PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| **Size:** | 30's |
| **Strength:** | 400 mg |
| **Dosage Form:** | Tablets |
| **Product Shape:** | Caplet |
| **Product Color:** | Dull red Color |
| **Product Imprint:** | Debossed with 'M' on one side and '400' on other |

### FOR GENERIC DRUG PRODUCTS

| | | | |
|---|---|---|---|
| | | | Authorized Generic |
| **I. Orange Book Rating:** | AB | *If Authorized Generic, other section fields are not applicable | |
| **II. Generic Equivalent to What Brand?:** | Avelox | | |

### DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| | | | |
|---|---|---|---|
| **Does supplier meet DSCSA definition of manufacturer?** | Yes | **GLN:** | 8904159670843 |
| **Is product exempt from DSCSA?** | No | | |
| **If yes, select exemption:** | | **GCP:** | 89041596 |
| **Other exemption - Write in:** | | | |
| **Is product repackaged?** | No | **If yes, was original product purchased direct from mfr?** | |
| **Is product sold by manufacturer's exclusive distributor?** | No | | |
| **Has FDA granted waiver/exception/exemption for product?** | No | **Provide source manufacturer for repackaged product** | |
| **If yes, attach documentation from FDA.** | | | |

### GTIN AND HIBCC PRODUCT INFORMATION

| Saleable Unit of Measure | | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|
| Yes | Item/Each | 1 | | 00372205001305 | 00372205001305 |
| NA | Box/Carton/Bundle/Inner Pack | NA | | NA | |
| Yes | Case | 120 | | 30372205001306 | |
| Yes | Pallet | 4800 | | 50372205001300 | |

### SPECIAL HANDLING AND STORAGE REQUIREMENTS*

**a. Temperature – Indicate the USP temperature range for this product.**

| | |
|---|---|
| Temperature Range | Controlled Room – between 20 and 25 C (68° – 77° F) |
| Other Temperature Range Requirement (write in) | NA |
| Notes | |
| Is this product to be shipped to customers on ice? | No |
| Is this product to be shipped to customers on dry ice? | No |

**b. Contact for temperature excursion questions:**

| | |
|---|---|
| **Name:** | |
| **Number:** | |
| **Group E-mail:** | |

| | | |
|---|---|---|
| **c. Special regulations for product in any states?** | No | |
| Special returns requirements for this product? | No | |
| **d. Store product (unit of sale) upright?** | No | |
| **Protect product (unit of sale) from light?** | No | |
| **e. Shelf life:** | 48 | **Months** |
| **Initial shelf life at launch (if different):** | 36 | **Months** |

### ORDER INFORMATION

| **Unit of Sale** | | **What is the NDC selling unit?** | |
|---|---|---|---|
| x | Bottle | 1 bottle of 30 Tablets | |
| | Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) | |
| | Ampule | | |
| | Glass | **Minimum order quantity?** | Yes |
| | Tube | | |
| | Vial Liquid Sgl | | |
| | Vial Liquid Multi | **If Yes, how many of which package type?** | |
| | Vial Powder Sql | 120 | Each |
| | Vial Power Multi | | Inner/Carton/Pack |
| | Other: Write In | | Case |

### PHARMACY ORDER / BILL UNIT

| **Rec. sell unit to customer?** | **Rx billing unit to pharmacy:** | |
|---|---|---|
| 1 bottle | x | Each |
| (Write-in, e.g. 1 Vial) | | Gram |
| | | Milliliter |

### ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| **Item/Each:** | 0.126 | NA | 1.53 | 3.28 | 54 | 1 |
| **Box/Carton/Bundle/ Inner Pack:** | NA | NA | NA | NA | NA | NA |
| **Case:** | 16.22 | 16.34 | 10.43 | 8.46 | 1441.81 | 120 |
| **Pallet:** | 688.63 | 47.24 | 39.37 | 39.76 | 73947.19 | 4,800 |

### COST INFORMATION

| | |
|---|---|
| **Regular Cost** | |
| **Invoice Cost (WAC) ($)** | $88.24 |
| As of date: | 7/23/2024 |

### WHOLESALER USE ONLY:

| | |
|---|---|
| **Vendor #:** | |
| **Whsl. Code #:** | |
| **Fineline Code:** | |

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

***Please provide any additional information on page 2.**

**See new p. 3 for Designated Drop Ship Only.**

**Signature:**

# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

**Version 2021**

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

| | |
|---|---|
| a. Cytotoxic? | No |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant? | |
| Is the product a CA Prop 65 carcinogen? | No |
| Is the product a CA Prop 65 reproductive toxicant? | No |
| Does the product label bear a CA Prop 65 warning? | No |
| c. Contact Hazard? | No |
| d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) | No |
| e. Does the product contain DEHP? | No |
| Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) | No |
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | No |
| Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) | No |
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | No |
| Is the product restricted for air shipment? If so, indicate restriction: | No |

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

| | |
|---|---|
| Is this a reportable quantity? | No |
| RQ Threshold: | |
| Is this a marine pollutant? | No |

Is this product shipped utilizing an authorized DOT exception or Special Permit?

No (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

### SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard

| | |
|---|---|
| Does the product have an Aerosol class? If yes, identify NFPA Storage Level: | No |
| NFPA Storage Level: | |
| Is the product a NIOSH hazardous drug? | No |
| If yes, indicate which: | |

### Hazardous Waste Identification

| | | | |
|---|---|---|---|
| EPA Hazardous Waste Code: | | Waste Characteristics | |

### REMS or REGISTRY RESTRICTIONS

| | | | |
|---|---|---|---|
| Is there a REMS on this product? | No | | |
| If Yes, is it managed with a pharmacy registry? | | | |
| Website URL: | | | |
| Med Guide Required | No | | |
| Limited Distribution Requirement | No | | |
| Comments / Details: (For example, iPledge program?) | | | |
| **REMS:** | No | | |
| REMS Program Manager Name: | | Phone: | |
| Supplier Manages REMS registry exclusively: | | | |
| Wholesale distributor support: | | | |
| Provider Name: | | DEA #: | |
| Site Enrollment Number assigned by Supplier: | | NCPDP#: | |
| | | NPI #: | |
| Comments | | | |
| **Registry:** | No | | |
| Registry Program Contact Name: | | Phone: | |
| Comments | | | |

### ADD'L STORAGE INFORMATION

Is the Product…

| | | | |
|---|---|---|---|
| Controlled Substance? | No | Controlled Substance Code | |
| Controlled by State(s)? | No | Listed Chemical (List I or II) | No |
| ARCOS Reportable? | No | If yes, indicate which: | |
| Schedule No. | | Is it a scheduled listed chemical product?: | No |

### CLASS OF TRADE RESTRICTION:

| | |
|---|---|
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | Yes |
| Restricted to retail pharmacy only: | No |
| Restricted to hospital, clinics, and physician offices only: | No |
| Restricted from US territories? (explain in comments) | No |
| Comments: | |

### RETURN INSTRUCTIONS

| | |
|---|---|
| Contact tel. # if product received damaged: | |
| Is product returnable for credit: | |
| URL/Link to returns policy: | |
| Special regulations or returns requirements for this product in certain states? | No |

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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**FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.**

## Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

## Standard Order Receipt and Processing

**Purchase order daily receipt cut off time by supplier**
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

## Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**
PO Receipt cut off time:
Days of week overnight is available:
Monday
Tuesday
Wednesday
Thursday
Friday

**Priority Overnight receipt available:**
PO Receipt Cut off time:

**Saturday Overnight receipt available:**
PO Receipt Cut off time:

Order receipt method: Phone: Phone #:
Fax: Fax #:
EDI:
Overnight Fees apply:
Other fees apply:

## Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

## Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

## Return Instructions

Contact # if product is received damaged:
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

## Miscellaneous Notes:

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?