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

Version 2024 | Introduction Type: New Item | Final Version | Date: 5/18/2026

PRODUCT INFORMATION

Company Name: Novadoz Pharmaceuticals, LLC
Application: ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k): 217398
NDA 505(b) Type:
Medical Device Class, if applicable:
DUNS: 08-110-9687
Proprietary Name (If Applicable) and Established Name: Olmesartan Medoxomil and Hydrochlorothiazide Tablets 20 mg/ 12.5 mg 30
Selling Unit NDC: 72205-147-30
Unit of Use NDC:
UPC: 372205147300
UDI
CVX Code:
MVX Code:
Description: Light Orange, Round, film-coated, biconvex tablets,debossed with "MO" on one side, and "8" on other side.
Active Ingredient(s): Olmesartan Medoxomil, Hydrochlorothiazide
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:
Product Therapeutic Classification:

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: P. Krishna Reddy
Number: 040-30449311
Group E-mail: krishna_p@msnlabs.com

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?

e. Shelf life: 36 Months
Initial shelf life at launch (if different): 36 Months

ADDITIONAL PRODUCT INFORMATION

The product is?
a legend device? No
if yes, enter class #
a product kit? No
if yes, list NDCs of component parts
reverse numbered? No
co-licensed? No
latex-free? No
preservative-free? No
correctional institution block? No
opioid? No
Cannabinoid? No
If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose, indicate NDC here: 72205-147-30

Is the Product… Direct-Ship Only
Is the Product… Neither
Orphan Drug Status
FDA Approval Status
Allergens Present
Country of Origin: India
Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 30
Strength: 20 mg/ 12.5 mg
Dosage Form: Tablets
Product Shape: Round, biconvex tablets
Product Color: Light Orange
Product Imprint: debossed with "MO" on one side, and "8" on other

ORDER INFORMATION

Unit of Sale
- X Bottle
- Box/Carton
- Ampule
- Glass
- Tube
- Vial Liquid Sgl
- Vial Liquid Multi
- Vial Powder Sql
- Vial Power Multi
- Other: Write In

What is the NDC selling unit? 1 Bottle of 30 Tablets
(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? Yes
If Yes, how many of which package type?
120 Each
Inner/Carton/Pack
Case

FOR GENERIC DRUG PRODUCTS

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

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)
HCPCS J-Code:
Rx billing unit to pharmacy:
Each
Gram
Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
Is product exempt from DSCSA? No
If yes, select exemption:
Other exemption - Write in:
Is product repackaged? No
Is product sold by manufacturer's exclusive distributor? No
Has FDA granted waiver/exception/exemption for product? No
If yes, attach documentation from FDA.

GLN: 8904159670843
GCP: 89041596
If yes, was original product purchased direct from mfr?
Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.087	NA	1.53	3.28	52	1
Box/Carton/Bundle/ Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	11.46	16.34	10.43	8.46	1441.63	120
Pallet:	498.42	47.24	39.37	39.76	73947	4,800

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Yes	Item/Each		1 Bottle of 30 Tablets		00372205147300	00372205147300
NA	Box/Carton/Bundle/Inner Pack		NA		NA	
Yes	Case		120 Bottles in Case		30372205147301	
Yes	Pallet		4800 Bottles in Pallet		50372205147305	

COST INFORMATION

Regular Cost
Invoice Cost (WAC) ($) $5.00
As of date: 5/18/2026

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: