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 40 mg/ 25 mg 30		
Selling Unit NDC:	72205-149-30	Unit of Use NDC:	UPC: 372205149304
UDI		CVX Code:	MVX Code:
Description:	Pink, Oval, film-coated, biconvex tablets,debossed with "MO" on one side, and "10" 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:			

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?	No		
co-licensed?	No	Allergens Present	
latex-free?	No		
preservative-free?	No		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No	Country of Origin	India
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	No
If Unit Dose, indicate NDC here:	72205-149-30		

PRODUCT DESCRIPTION INFORMATION

Size:	30
Strength:	40 mg/ 25 mg
Dosage Form:	Tablets
Product Shape:	Oval, biconvex tablets
Product Color:	Pink
Product Imprint:	debossed with "MO" on one side, and "10" on

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?:

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	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Yes	Item/Each	1 Bottle of 30 Tablets			00372205149304	00372205149304
NA	Box/Carton/Bundle/Inner Pack	NA			NA	
Yes	Case	120 Bottles in Case			30372205149305	
Yes	Pallet	4800 Bottles in Pallet			50372205149309	

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

ORDER INFORMATION

Unit of Sale

X	Bottle
	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sgl
	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

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

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.102	NA	1.53	3.28	52	1
Box/Carton/Bundle/ Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	12.22	16.34	10.43	8.46	1441.63	120
Pallet:	568.26	47.24	39.37	39.76	73947	4,800

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: