



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

Version 2024 Introduction Type: Final Version Date:

PRODUCT INFORMATION	
Company Name:	Novadoz Pharmaceuticals LLC
Application Number for NDA/ANDA/BLA; PMA/510(k):	216084
Application:	ANDA
Medical Device Class, if applicable:	
DUNS:	08-110-9687
Proprietary Name (If Applicable) and Established Name:	Glycopyrrolate Oral Solution 1 mg/5 mL (0.2 mg/mL) 16 oz. (473 mL)
Selling Unit NDC:	72205-070-72
Unit of Use NDC:	
UPC:	372205070721
CVX Code:	
MXV Code:	
Description:	1 mg/5 mL clear, cherry-flavored solution
Active Ingredient(s):	Glycopyrrolate, USP
URL for Additional Product Information:	
Address:	20 Duke Road
City:	Piscataway
Key Contact:	
Phone Number:	908-360-1500
Product Therapeutic Classification:	
Address 2:	Suite A
State:	NJ
Zip:	08854
Email:	Sales@novadozpharma.com
Fax:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Other Temperature Range Requirement (write in)	<input type="text"/>
Notes	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Group E-mail:	<input type="text"/>
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="text"/>
d. Store product (unit of sale) upright?	
	<input type="text" value="Yes"/>
e. Shelf life:	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Size:	16 fl. oz. (473 mL)
a legend device?	<input type="text" value="No"/>	Strength:	1 mg/5 mL
if yes, enter class #		Dosage Form:	Oral Solution
a product kit?	<input type="text" value="No"/>	Product Shape:	N/A
if yes, list NDCs of component parts reverse numbered?		Product Color:	Clear
co-licensed?	<input type="text" value="No"/>	Product Imprint:	N/A
latex-free?	<input type="text" value="Yes"/>		
preservative-free?	<input type="text" value="No"/>		
correctional institution block?	<input type="text" value="No"/>		
opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text" value="72205-070-72"/>		
Is the Product... Is the Product... Orphan Drug Status	<input type="text"/>		
FDA Approval Status	<input type="text"/>		
Allergens Present	<input type="text" value="No"/>		
Country of Origin	<input type="text" value="USA"/>		
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text"/>		

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 carton of 1 bottle"/>
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="12"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	<input type="text"/>
	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AA"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Cuvposa"/>
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text"/>
If yes, attach documentation from FDA.	<input type="text"/>
GLN:	<input type="text" value="0382374000016"/>
GCP:	<input type="text" value="0382374"/>
If yes, was original product purchased direct from mfr?	<input type="text"/>
Provide source manufacturer for repackaged product	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	1.29	3.14	2.44	7.48	57.31	1
Case:	NA	NA	NA	NA	NA	NA
Pallet:	16.52	13.78	8.46	8.85	1031.72	12
	965.36	47.25	39.37	41.33	76883.41	672

GTIN AND HIBCC PRODUCT INFORMATION					
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each		1 Carton of 1 HDPE Bottle		00372205070721	00372205070721
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		NA		NA	
<input checked="" type="checkbox"/> Case		12 Cartons per case		30372205070722	
<input checked="" type="checkbox"/> Pallet		672 Cartons per pallet		50372205070726	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$60.00"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text" value="8/13/2025"/>	Fineline Code:	<input type="text"/>

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
- Is the product a CA Prop 65 carcinogen?
- Is the product a CA Prop 65 reproductive toxicant?
- Does the product label bear a CA Prop 65 warning?

- c. Contact Hazard?
- d. Does this product require special clean-up instructions?
- (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

Is this product regulated for shipment by DOT?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is this product regulated for shipment by IATA?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity?
RQ Threshold:

Is this a marine pollutant?

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

ADD'L STORAGE INFORMATION

Is the Product...

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

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:

SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

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:

Registry Program Contact Name: Phone:

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?

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

