



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

Version 2021

Introduction Type: New Item

Final Version

Date: 01.06.2023

PRODUCT INFORMATION

Company Name: Auromedics Pharma LLC **Application:** ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): _____

Medical Device Class, if applicable: _____

DUNS: _____

Proprietary Name (If Applicable) and Established Name: _____

Selling Unit NDC: 55150-459-10 **Unit of Use NDC:** 55150-459-01 **UPC:** 355150459100

UDI _____ **CVX Code:** _____ **MVX Code:** _____

Description: Carboprost Tromethamine Injection, USP 250 mcg/ml (10 vials)

Active Ingredient(s): _____

URL for Additional Product Information: _____

Address: 279 Princeton-Hightstown Road **Address 2:** _____

City: East Windsor **State:** NJ **Zip:** 08520

Key Contact: _____ **Email:** _____

Phone Number: 888-238-7880 **Fax:** 732-355-9449

Product Therapeutic Classification: _____

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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

Temperature Range: Cold – between 2 and 8 C (36° – 46° F)

Other Temperature Range Requirement (write in): _____

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?

Special returns requirements for this product?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life: 18 Months

Initial shelf life at launch (if different): _____ Months

ADDITIONAL PRODUCT INFORMATION

The product is?

a legend device?

if yes, enter class # _____

a product kit?

if yes, list NDCs of component parts reverse numbered? _____

co-licensed?

latex-free?

preservative-free?

correctional institution block?

opioid?

Cannabinoid?

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here: _____

Is the Product... Is the Product... 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: 10 x 1 mL Single-Dose Vial

Strength: 250 mcg per mL

Dosage Form: Solution

Product Shape: _____

Product Color: _____

Product Imprint: _____

ORDER INFORMATION

Unit of Sale

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Powder Multi

Other: Write In _____

What is the NDC selling unit? 55150-459-10

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? _____

If Yes, how many of which package type?

Each

Inner/Carton/Pack

Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: _____ Authorized Generic *If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?: _____

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? _____

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

Each

Gram

Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No

Is product exempt from DSCSA? Yes No

If yes, select exemption: _____

Other exemption - Write in: _____

Is product repackaged? Yes No

Is product sold by manufacturer's exclusive distributor? Yes No

Has FDA granted waiver/exception/exemption for product? Yes No

If yes, attach documentation from FDA. _____

GLN: _____

GCP: _____

If yes, was original product purchased direct from mfr? Yes No

Provide source manufacturer for repackaged product _____

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.17636	3.54	1.38	1.77	8.647	10 vials
Box/Carton/Bundle/Inner Pack:						
Case:	23.12	15.5511	12.0078	8.6614	1617.382	1200 vials
Pallet:	Air & Sea-865.352	48	40	Air & Sea-39.65	Air & Sea-76218	Air & Sea-43200 vials

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	10		00355150459100	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	1200		50355150459105	
<input checked="" type="checkbox"/> Pallet	43200		70355150459109	

COST INFORMATION

Regular Cost _____

Invoice Cost (WAC) (\$) _____

As of date: _____

WHOLESALE USE ONLY:

Vendor #: _____

Whsl. Code #: _____

Fineline Code: _____