



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

Version 2020 Introduction Type: Final Version Date:

PRODUCT INFORMATION	
Company Name:	Auromedics LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	211121
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	NICARDIPINE Hydrochloride Injection USP
Selling Unit NDC:	55150-183-10
Unit of Use NDC:	55150-183-01
UPC:	355150183104
CVX Code:	
MXV Code:	
Description:	NICARDIPINE Hydrochloride Injection USP 25 mg/10 mL [2.5 mg/mL] (10's)
Active Ingredient(s):	NICARDIPINE Hydrochloride Injection USP
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Zip:	08520
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	Calcium channel blocking agents, dihydropyridines

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)	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Notes	Protect from light.
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:	Steve Lucas
Number:	732-823-4122
Group E-mail:	slucas@aurobindowsa.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	18 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	No	Is the Product... Direct-Ship Only	10 x 10 mL Single Dose Vials
if yes, enter class # a product kit?	No	Is the Product... Orphan Drug Status	25 mg per 10 mL (2.5 mg / mL)
if yes, list NDCs of component parts reverse numbered?	No	FDA Approval Status	Liquid
co-licensed?	No	Allergens Present	
latex-free?	Yes	Country of Origin	Vial Pack
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
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:			

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 Box of 10 Vials
<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? 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="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> Case
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FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Cardene I.V. Injection, 25 mg/10 mL
<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:
10 Vials	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
GLN:	
If yes, select exemption:	
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
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.4874	5.31	2.17	2.36	27.193572	10
Case:	14.052	14.763	12.205	7.126	1283.9799	24
Pallet:	918.331	48	40	54.88	105369.6	1,512

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	10		00355150183104	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input type="checkbox"/> Case	24		50355150183109	
<input type="checkbox"/> Pallet	1512		70355150183103	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$212.36	Whsl. Code #:	
As of date:	6/29/2021	Fineline Code:	

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