



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

Version 2020

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	<input type="text" value="Auromedics LLC"/>	Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="210625"/>		
DUNS:	<input type="text" value="968961354"/>		
Proprietary Name (If Applicable) and Established Name:	<input type="text" value="Fosaprepitant for Injection"/>		
Selling Unit NDC:	<input type="text" value="55150-299-01"/>	Unit of Use NDC:	<input type="text" value="55150-299-01"/>
UDI		UPC:	<input type="text" value="355150299010"/>
		CVX Code:	
		MXV Code:	
Description:	<input type="text" value="Fosaprepitant for Injection 150 mg per vial (Mono Pack)"/>		
Active Ingredient(s):	<input type="text" value="Fosaprepitant"/>		
URL for Additional Product Information:			
Address:	<input type="text" value="279 Princeton-Hightstown Road"/>	Address 2:	
City:	<input type="text" value="East Windsor"/>	State:	<input type="text" value="NJ"/>
Phone Contact:		Email:	<input type="text" value="08520"/>
Phone Number:	<input type="text" value="888-238-7880"/>	Fax:	<input type="text" value="732-355-9449"/>
Product Therapeutic Classification:	<input type="text" value="Antiemetic - Emetogenic Therapy Adjunct"/>		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	<input type="text" value="Cold – between 2 and 8 C (36° – 46° F)"/>
Other Temperature Range Requirement (write in)	<input type="text" value="Fosaprepitant for Injection vial must be refrigerated at 2° to 8°C (36° to 46°F)."/>
Notes	<input type="text" value="The reconstituted final drug solution is stable for 24 hours at ambient room temperature [at or below"/>
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" value="Steve Lucas"/>
Number:	<input type="text" value="732-823-4122"/>
Group E-mail:	<input type="text" value="slucas@auromedics.com"/>
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="text"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text"/>
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>
if yes, enter class # a product kit?	<input type="text"/>	Is the Product... Orphan Drug Status	<input type="text"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text"/>	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Allergens Present	<input type="text"/>
latex-free?	<input type="text" value="No"/>	Country of Origin	<input type="text"/>
preservative-free?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
correctional institution block?	<input type="text" value="No"/>	Size:	<input type="text" value="1 x 10 mL Single-Dose Vial"/>
opioid?	<input type="text" value="No"/>	Strength:	<input type="text" value="150 mg per vial"/>
Cannabinoid?	<input type="text" value="No"/>	Dosage Form:	<input type="text" value="Lyo (Powder)"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Product Shape:	<input type="text" value="Vial Pack"/>
If Unit Dose, indicate NDC here:	<input type="text"/>	Product Color:	<input type="text"/>
		Product Imprint:	<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 Vial"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write In	
	If Yes, how many of which package type?
	<input type="text" value="1"/> Each
	<input type="text"/>
	<input type="text"/>
	<input type="text"/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Emend® for Injection"/>
<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" value="1 Vial"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Gram
	<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:	GLN: <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" value="No"/>
	If Yes, was original product purchased direct from mfr? <input type="text"/>
	If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	0.0396	1.42	1.42	2.36	4.758704	1
Box/Carton/Bundle/Inner Pack:	3.724	15.2	9.49	2.99	431.30152	60
Case:	17.44	20.079	15.945	7.677	2457.8657	240
Pallet:	451.591	47.24	39.37	51.06	94963.37	5,760

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150299010	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	60		30355150299011	
<input type="checkbox"/> Case	240		50355150299015	
<input type="checkbox"/> Pallet	5,760		70355150299019	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$65.00"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text" value="5/24/2021"/>	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? No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a CA Prop 65 reproductive toxicant? No
 - Does the product label bear a CA Prop 65 warning? No
- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP? No

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? No

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? No

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

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes
- Restricted to retail pharmacy only: No
- Restricted to hospital, clinics, and physician offices only: No
- Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug? No
- If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics

REMS or REGISTRY RESTRICTIONS

- Is there a REMS on this product? No
- 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: PCPDP#:
 - NPI #:
 - Comments
- Registry:**
 - Registry Program Contact Name: Phone:
 - Comments

RETURN INSTRUCTIONS

- Contact tel. # if product received damaged: 888-238-7880
- Is product returnable for credit: Yes
- URL/Link to returns policy: <http://auomedics.com/policies/return-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:



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI <input type="text"/> b. Autofax <input type="text"/> Fax Number: <input type="text"/> c. Fax <input type="text"/> Fax Number: <input type="text"/> d. Phone only <input type="text"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="text"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="text"/> Ships for second day receipt: <input type="text"/> Ships regular ground for 3-10 days receipt: <input type="text"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="text"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="text"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="text"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="text"/> Other fees apply: <input type="text"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/> Restricted to retail pharmacy only: <input type="text"/> Restricted to hospital, clinics, and physician offices only: <input type="text"/> Restricted from US territories? (explain in comments) <input type="text"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="text"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="text"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="text"/> Is product order for restocking purposes? <input type="text"/>