



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

Version 2021

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Monaghan Medical Corporation
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	K181649
Medical Device Class, if applicable:	Class II without exemptions
DUNS:	056332380
Proprietary Name (If Applicable) and Established Name:	AEROCHAMBER PLUS® FLOW-VU® Anti-Static Valved Holding Chamber - Large Mask
Selling Unit NDC:	Unit of Use NDC:
UDI	UPC: 604351503120
	CVX Code:
	MVX Code:
Description:	AEROCHAMBER PLUS® FLOW-VU® Anti-Static Valved Holding Chamber with Large, Blue Mask for use with either Metered Dose Inhalers or Soft Mist Inhalers
Active Ingredient(s):	
URL for Additional Product Information:	https://www.monaghanmed.com/product/aerochamber-plus-flow-vu-avhc/
Address:	153 Industrial Boulevard
City:	Plattsburgh
Key Contact:	Lisa Badura
Phone Number:	(262) 433-8319
Product Therapeutic Classification:	NVP

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Avoid Excessive Heat – above 40 C (>104° F)
Other Temperature Range Requirement (write in)	Storage and operating range 41°F–104°F (5°C–40°C) at 15 to 95% relative humidity
Notes	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> 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?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	<input type="checkbox"/> Yes	Is the Product... Direct And Drop-Ship	
if yes, enter class #	Class II	Is the Product... Neither	
a product kit?	<input type="checkbox"/> No	Orphan Drug Status	
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	<input type="checkbox"/> No	Allergens Present	None
co-licensed?	<input type="checkbox"/> No	Country of Origin	USA
latex-free?	<input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> Yes
preservative-free?	<input type="checkbox"/> Yes		
correctional institution block?	<input type="checkbox"/> No		
opioid?	<input type="checkbox"/> No		
Cannabinoid?	<input type="checkbox"/> No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:			
		Size:	1
		Strength:	
		Dosage Form:	
		Product Shape:	Cylinder
		Product Color:	Orange
		Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 Box of 1 Valved Holding Chamber
<input checked="" type="checkbox"/> X Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity?
<input type="checkbox"/> Tube	<input type="checkbox"/> Yes
<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"/> 1 Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> 12 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text"/>
II. Generic Equivalent to What Brand?:	<input type="text"/>
<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"/> 1 Each	<input type="text"/> 1 Each
(Write-in, e.g. 1 Vial)	<input type="text"/> Gram
	<input type="text"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/>
Is product exempt from DSCSA?	<input type="checkbox"/>
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/>
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/>
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/>
If yes, attach documentation from FDA.	
GLN:	<input type="text"/>
GCP:	<input type="text"/>
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
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:	0.278	8.25	4.125	3.625	123.36328	1
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	4.335	16.875	12.625	7.75	1651.1133	12
Pallet:	195	48	40	43.75	84000	480

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> X Item/Each	1		00604351503129	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input type="checkbox"/> Case				
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$49.04	Whsl. Code #:	
As of date:		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:

Lisa Badura



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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? (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No

- 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) No

- 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: No

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit? No (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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No
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 No
Limited Distribution Requirement No
Comments / Details: (For example, iPledge program?)

REMS: No
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No
Wholesale distributor support: No
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: No
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: (518) 561-7330

Is product returnable for credit: Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?



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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="checkbox"/> Yes b. Autofax <input type="checkbox"/> Yes Fax Number: (518) 561-5660 c. Fax <input type="checkbox"/> Yes Fax Number: (518) 561-5660 d. Phone only <input type="checkbox"/> No Phone No.: e. Supplier Web Site only <input type="checkbox"/> No Site Address: Minimum Order Quantity: 12 Units Supplier's Customer Service Number: (518) 561-5660 Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 12:00 PM (Noon) Eastern Shipping lead time of PO: Hours 10 Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="checkbox"/> Yes Drop Ship service fee billed with each order: <input type="checkbox"/> Yes Drop Ship miscellaneous fees billed: <input type="checkbox"/> Yes Comments: Customer to pay for any expedited shipping fees; billed with each order	Overnight receipt available: <input type="checkbox"/> Yes PO Receipt cut off time: 10:00 AM Eastern Days of week overnight is available: <input checked="" type="checkbox"/> Monday <input checked="" type="checkbox"/> Tuesday <input checked="" type="checkbox"/> Wednesday <input checked="" type="checkbox"/> Thursday <input checked="" type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> Yes PO Receipt Cut off time: 10:00 AM EST Saturday Overnight receipt available: <input type="checkbox"/> No PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: <input type="checkbox"/> Yes Other fees apply: <input type="checkbox"/> Yes
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes Restricted to retail pharmacy only: <input type="checkbox"/> No Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments:	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Contact # if product is received damaged: (518) 561-7330 Is product returnable for credit: <input type="checkbox"/> Yes URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No If so, which states? Other requirements? Comments?
Miscellaneous Notes:	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? <input type="checkbox"/> No Is product order for restocking purposes? <input type="checkbox"/> Yes