



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

Version 2021 Introduction Type:  New Item  Final Version Date:

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA  
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 214616  
**Medical Device Class, if applicable:** \_\_\_\_\_  
**DUNS:** 826774775  
**Proprietary Name (If Applicable) and Established Name:** Fosaprepitant Dimethylglumine 150mg/vial 10m/l  
**Selling Unit NDC:** 31722-165-31 **Unit of Use NDC:** \_\_\_\_\_ **UPC:** 33172216531  
**UDI:** \_\_\_\_\_ **CVX Code:** \_\_\_\_\_ **MX Code:** \_\_\_\_\_  
**Description:** Powder for Injection (Intravenous), white to off white powder. When reconstituted, the color should be clear, colorless to a pale yellow solution. The clarity is clear.  
**Active Ingredient(s):** Fosaprepitant Dimethylglumine  
**URL for Additional Product Information:** [www.camberpharma.com](http://www.camberpharma.com)  
**Address:** 800 Centennial Ave **Address 2:** \_\_\_\_\_  
**City:** Piscataway **State:** NJ **Zip:** 08854  
**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
**Phone Number:** 732-529-0430 **Fax:** 732-562-8788  
**Product Therapeutic Classification:** Antiemetics

**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:** Soma Raju  
**Number:** 732-529-0423  
**Group E-mail:** [somaraju@heterousa.com](mailto:somaraju@heterousa.com)  
**c. Special regulations for product in any states?**  
 Special returns requirements for this product?   
**d. Store product (unit of sale) upright?**  No  
**Protect product (unit of sale) from light?**  No  
**e. Shelf life:**  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/>	Size:	10m/l
if yes, enter class # _____	Is the Product... Neither <input type="checkbox"/>	Strength:	150mg
a product kit? <input type="checkbox"/> No	Orphan Drug Status <input type="checkbox"/>	Dosage Form:	Powder for Injection (Intrav)
if yes, list NDCs of component parts reverse numbered? _____	FDA Approval Status _____	Product Shape:	N/A
co-licensed? <input type="checkbox"/> No	Allergens Present _____	Product Color:	White to off White
latex-free? <input type="checkbox"/> Yes	Country of Origin <input type="text" value="India"/>	Product Imprint:	N/A
preservative-free? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		
correctional institution block? <input type="checkbox"/> Yes			
opioid? <input type="checkbox"/> Yes			
Cannabinoid? <input type="checkbox"/> No			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No			
If Unit Dose, indicate NDC here: _____			

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	31722-165-31
<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="checkbox"/> 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="1"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In _____	<input type="text"/> Case

**FOR GENERIC DRUG PRODUCTS**

Authorized Generic \*If Authorized Generic, other section fields are not applicable  
**I. Orange Book Rating:**   
**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  
 Is product exempt from DSCSA?  No  
**GLN:** 0331722000000  
**GCP:** \_\_\_\_\_  
 If yes, select exemption: \_\_\_\_\_  
 Other exemption - Write in: \_\_\_\_\_  
 Is product repackaged?  No  
 Is product sold by manufacturer's exclusive distributor?  No  
 Has FDA granted waiver/exception/exemption for product?  No  
 If yes, attach documentation from FDA. \_\_\_\_\_  
 If yes, was original product purchased direct from mfr?   
 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:	0.02	2.5	1	1	2.5	1
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	4.9	4	15	11	660	48
Pallet:					0	

**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	1		00331722165310	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	48		20331722165314	
<input type="checkbox"/> Pallet				

**COST INFORMATION** **WHOLESALE USE ONLY:**

**Regular Invoice Cost (WAC) (\$)**   
**As of date:** \_\_\_\_\_  
**Vendor #:** \_\_\_\_\_  
**Whsl. Code #:** \_\_\_\_\_  
**Fineline Code:** \_\_\_\_\_



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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?
  - 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)

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

### CLASS OF TRADE RESTRICTION:

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

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?  No  Yes  
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  Yes  
If Yes, is it managed with a pharmacy registry?  No  Yes  
Website URL:

Med Guide Required  No  Yes  
Limited Distribution Requirement  No  Yes  
Comments / Details: (For example, iPledge program?)

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

Comments

**Registry:**  No  Yes  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647  
Is product returnable for credit:  No  Yes

URL/Link to returns policy:  contact - customerservice@camberpharma.com

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

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

