



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:

Final Version

Date:

**PRODUCT INFORMATION**

Company Name:  Application:   
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):   
 DUNS:   
 Proprietary Name (If Applicable) and Established Name:   
 Selling Unit NDC:  Individual Unit NDC:  UPC:   
 UDI:  CVX Code:  MVX Code:   
 Description:   
 Active Ingredient(s):   
 URL for Additional Product Information:   
 Address:  Address 2:   
 City:  State:  Zip:   
 Key Contact:  Email:   
 Phone Number:  Fax:   
 Product Therapeutic Classification:

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range:   
 Other Temperature Range Requirement (write in):   
 Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?

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

**ADDITIONAL PRODUCT INFORMATION**

Is the Product...  
 a legend device?   
 reverse numbered?   
 co-licensed?   
 Is the Product...  
 Direct-Ship Only   
 Is the Product...  
 Unit of Use   
 If Unit Dose, is item bar coded to unit dose for hospital scanning?   
 If Unit Dose NDC, indicate NDC here:   
 Country of Origin:   
 Is this product covered under the Trade Agreements Act (TAA)?

**PRODUCT DESCRIPTION INFORMATION**

Size:   
 Strength:   
 Dosage Form:   
 Product Shape:   
 Product Color:   
 Product Imprint:

**ORDER INFORMATION**

Unit of Sale  
 yes Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Power Multi  
 Other: Write In

What is the NDC selling unit?  
  
 (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?  GLN:   
 Is product exempt from DSCSA?   
 If yes, select exemption:  
 Other exemption - Write in:   
 Is product repackaged?   
 Is product sold by manufacturer's exclusive distributor?   
 Has FDA granted waiver/exception/exemption for product?   
 If Yes, was original product purchased direct from mfr?   
 If yes, attach documentation from FDA.

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.13	NA	3.8	2.1	#VALUE!	60 tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	3.3	11.5	4.1	7.2	339.48	24 bottles per Case
Pallet:	730	48	54	40	103680	220 Cases per Pallet
UPC:	Case:	350228424608				
	Carton:					

**GTIN PRODUCT INFORMATION**

Serialized? If not, when? Items aggregated?	Yes <input type="text"/>	Level	Saleable Unit	Quantity	GTIN-14
	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	1	00350228424608
	<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	24	20350228424602
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		
	<input type="checkbox"/>		<input type="checkbox"/>		

**COST INFORMATION**

Regular Cost:   
 Invoice Cost (WAC) (\$):   
 Federal Excise Tax Per Unit of Sale:   
 As of date:

**WHOLESALE USE ONLY:**  
 Vendor #:   
 Whsl. Code #:   
 Finline Code:

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.)

e. Does the product contain DEHP?  No

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

(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?  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#

SDS Hazard Classification

Organic                       Corrosive  
 Inorganic                       Oxidizer  
 Steroid/Androgen             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:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
 If Yes, is it managed with a pharmacy registry?   
 Website URL:

Comments / Details: (For example, iPledge program?)

**REMS:**   
 REMS Program Manager Name:  Phone:   
 Supplier Manages REMS registry exclusively:   
 Wholesale distributor support:   
 Provider Name:   
 Site Enrollment Number assigned by Supplier:  DEA #:   
 PCPDP #:   
 NPI #:

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance?  No

Controlled by State(s)?  No

ARCOS Reportable?

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:  
 Is it a scheduled listed chemical product?

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

Comments

**Registry:**   
 Registry Program Contact Name:  Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  No  
 If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

