



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

Version 2020

Introduction Type:  New Item

Final Version

Date: 7/10/2024

PRODUCT INFORMATION	
Company Name:	<input type="text" value="Xiromed LLC"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="212993"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (if Applicable) and Established Name:	<input type="text" value="Irinotecan Hydrochloride"/>
Selling Unit NDC:	<input type="text" value="70700-169-22"/>
UDI	<input type="text" value="Unit of Use NDC:"/>
CVX Code:	<input type="text" value="UPC: 370700169223"/>
MXV Code:	<input type="text" value=""/>
Description:	<input type="text" value="Irinotecan Hydrochloride Injection USP 40mg/2ml"/>
Active Ingredient(s):	<input type="text" value="Irinotecan Hydrochloride"/>
URL for Additional Product Information:	<input type="text" value=""/>
Address:	<input type="text" value="180 Park Ave"/>
City:	<input type="text" value="Florham Park"/>
Key Contact:	<input type="text" value="Xiromed Regulatory"/>
Phone Number:	<input type="text" value="844-947-6633"/>
Product Therapeutic Classification:	<input type="text" value=""/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	<input type="text" value=""/>
Notes	<input type="text" value=""/>
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:	<input type="text" value="Xiromed Quality"/>
Number:	<input type="text" value="844-947-6633"/>
Group E-mail:	<input type="text" value="US-Quality-Xiromed@xiromed.com"/>
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> Yes
Protect product (unit of sale) from light?	<input type="checkbox"/> Yes
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text" value=""/>

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"/> Neither
If yes, enter class # a product kit?	<input type="text" value=""/>	Orphan Drug Status	<input type="checkbox"/>
If yes, list NDCs of component parts reverse numbered?	<input type="text" value=""/>	FDA Approval Status	<input type="text" value=""/>
co-licensed?	<input type="checkbox"/> No	Allergens Present	<input type="checkbox"/> Not made with natural rubber latex. Free from Gluten, Lactose, Sweeteners, Soy, and Gelatin
latex-free?	<input type="checkbox"/> Yes	Country of Origin	<input type="text" value="India"/>
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"/> 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:	<input type="text" value=""/>		
Size:	<input type="text" value="2mL Vial"/>	Strength:	<input type="text" value="40MG/2ML (20MG/ML)"/>
Dosage Form:	<input type="text" value="Injectable"/>	Product Shape:	<input type="text" value=""/>
Product Color:	<input type="text" value=""/>	Product Imprint:	<input type="text" value=""/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Box of 10 Vials"/>
<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 checked="" type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="10"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value=""/>
<input type="checkbox"/> Vial Power Multi	<input type="text" value=""/>
<input type="checkbox"/> Other: Write In	<input type="text" value=""/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="CAMPTOSAR"/>
<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 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?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	GLN: <input type="text" value="0370700000007"/>
Other exemption - Write in:	<input type="text" value=""/>
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
	If Yes, was original product purchased direct from mfr? <input type="checkbox"/>
	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	
Case:	0.551	3.1496	7.874	2.559	63.463073	10
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	1		00370700169223	
Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	10		10370700169220	
Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$14.54"/>	Whsl. Code #:	<input type="text" value=""/>
As of date:	<input type="text" value=""/>	Fineline Code:	<input type="text" value=""/>

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:



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

Version 2020

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?  Yes

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?  Yes

d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.)  Yes

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?

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?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity?  Yes

RQ Threshold:  Sodium Hydroxide - 454kg  Hydrogen Chloride - 2270kg

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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

### SDS Hazard Classification

Organic       Corrosive

Inorganic       Oxidizer

Steroid/Androgen       Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
 If yes, indicate which:  Yes  No  
 Group 1 items (antineoplastic)

### 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?

Website URL:

Med Guide Required  No  Yes

Limited Distribution Requirement  No  Yes

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:

Is product returnable for credit:

URL/Link to returns 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:

