



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

Version 2020 Introduction Type: Post Launch Change Final Version Date:

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="210123"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (If Applicable) and Established Name:	<input type="text" value="FLUOROURACIL"/>
Selling Unit NDC:	<input type="text" value="70700-187-23"/>
UDI	<input type="text"/>
Description:	<input type="text" value="Fluorouracil Injection, USP 1g/20mL 10x20mL Single-Dose Vials"/>
Active Ingredient(s):	<input type="text" value="FLUOROURACIL"/>
URL for Additional Product Information:	<input type="text"/>
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"/>
Application:	<input type="text" value="ANDA"/>
Unit of Use NDC:	<input type="text" value="370700187234"/>
UPC:	<input type="text"/>
CVX Code:	<input type="text"/>
MX Code:	<input type="text"/>
Address 2:	<input type="text" value="Suite 101"/>
State:	<input type="text" value="NJ"/>
Zip:	<input type="text" value="07932"/>
Email:	<input type="text" value="usregulatory@xiromed.com"/>
Fax:	<input type="text" value="862-286-0932"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Temperature Range	<input type="text"/>
Other Temperature Range Requirement (write in)	<input type="text"/>
Notes	<input type="text"/>
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:	<input type="text"/>
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="text" value="No"/>
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="Yes"/>
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
e. Shelf life:	<input type="text" value="24"/>
Initial shelf life at launch (if different):	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text"/>
a legend device?	<input type="text"/>	Is the Product... Neither	<input type="text"/>
if yes, enter class #	<input type="text"/>	Orphan Drug Status	<input type="text"/>
a product kit?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
if yes, list NDCs of component parts	<input type="text"/>	Allergens Present	<input type="text" value="Container closure is not made with natural rubber latex."/>
reverse numbered?	<input type="text" value="No"/>	Country of Origin	<input type="text" value="India"/>
co-licensed?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
latex-free?	<input type="text" value="Yes"/>	Size:	<input type="text" value="10 x 20mL Single-dose vials"/>
preservative-free?	<input type="text" value="Yes"/>	Strength:	<input type="text" value="1GM/20ML (50MG/ML)"/>
correctional institution block?	<input type="text" value="Yes"/>	Dosage Form:	<input type="text" value="INJECTABLE"/>
opioid?	<input type="text" value="No"/>	Product Shape:	<input type="text"/>
Cannabinoid?	<input type="text" value="No"/>	Product Color:	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Product Imprint:	<input type="text"/>
If Unit Dose, indicate NDC here:	<input type="text"/>		

ORDER INFORMATION	
Unit of Sale	<input type="text" value="1 Box containing 10 Vials"/>
What is the NDC selling unit?	<input type="text" value="1 Box containing 10 Vials"/>
Minimum order quantity?	<input type="text" value="Yes"/>
If Yes, how many of which package type?	<input type="text" value="12"/>
Each	<input type="text"/>
Inner/ Carton/ Pack	<input type="text"/>
Case	<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"/>
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	<input type="text" value="1 Box containing 10 Vials"/>
Rx billing unit to pharmacy:	<input type="text" value="x"/>
Each	<input type="text"/>
Gram	<input type="text"/>
Milliliter	<input type="text"/>

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:	<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"/>
GLN:	<input type="text" value="0370700000007"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
If yes, attach documentation from FDA.	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	1.168	6.457	2.559	2.874	47.488433	1
Case:	15.653	11.024	6.89	9.449	717.7022	12
Pallet:					0	

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		00370700187234	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		20370700187238	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$120.00"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

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:



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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? 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? 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:

Passenger
 Cargo
 Passenger & Cargo

Is this a reportable quantity? Yes
 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:

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? 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
 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:

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:



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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"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> 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="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
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="checkbox"/> 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="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> 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="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> 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="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	Return Instructions
<input type="text"/>	<input type="text"/>
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>