



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="201501"/>
DUNS:	<input type="text" value="080228637"/>
Proprietary Name (if Applicable) and Established Name:	<input type="text" value="Acyclovir Ointment"/>
Selling Unit NDC:	<input type="text" value="70700-107-16"/>
UDI	<input type="text" value=""/>
Description:	<input type="text" value="Acyclovir Ointment USP, 5% - 30g Tube"/>
Active Ingredient(s):	<input type="text" value="Acyclovir"/>
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.	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Temperature Range	<input type="text" value=""/>
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="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" value="Xiromed Quality"/>
Name:	<input type="text" value="844-947-6633"/>
Number:	<input type="text" value="US-Quality-Xiromed@xiromed.com"/>
Group E-mail:	<input type="text" value=""/>
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=""/>
Protect product (unit of sale) from light?	<input type="text" value=""/>
e. Shelf life:	<input type="text" value="24"/>
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="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value=""/>
if yes, enter class #	<input type="text" value=""/>	Is the Product... Neither	<input type="text" value=""/>
if yes, list NDCs of component parts	<input type="text" value=""/>	Orphan Drug Status	<input type="text" value=""/>
reverse numbered?	<input type="text" value="No"/>	FDA Approval Status	<input type="text" value=""/>
co-licensed?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Not made with natural rubber latex."/>
latex-free?	<input type="text" value="No"/>	Country of Origin	<input type="text" value="Spain"/>
preservative-free?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
correctional institution block?	<input type="text" value="Yes"/>	Size:	<input type="text" value="30gm"/>
opioid?	<input type="text" value="No"/>	Strength:	<input type="text" value="5%"/>
Cannabinoid?	<input type="text" value="No"/>	Dosage Form:	<input type="text" value="Topical"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>	Product Shape:	<input type="text" value=""/>
If Unit Dose, indicate NDC here:	<input type="text" value=""/>	Product Color:	<input type="text" value=""/>
		Product Imprint:	<input type="text" value=""/>

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Bottle
What is the NDC selling unit?	<input type="text" value="1 Box containing 1 Tube"/>
<input checked="" type="checkbox"/> Box/ Carton	<input type="text" value=""/>
Ampule	<input type="text" value=""/>
Glass	<input type="text" value=""/>
Tube	<input type="text" value=""/>
Vial Liquid Sgl	<input type="text" value=""/>
Vial Liquid Multi	<input type="text" value=""/>
Vial Powder Sgl	<input type="text" value=""/>
Vial Power Multi	<input type="text" value=""/>
Other: Write In	<input type="text" value=""/>
Minimum order quantity?	<input type="text" value="Yes"/>
If Yes, how many of which package type?	<input type="text" value="48"/>
	<input type="text" value=""/>
	<input type="text" value=""/>
	<input type="text" value=""/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="ZOVIRAX"/>
<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 Tube"/>
Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="text" value=""/>
	<input type="text" value=""/>
	<input type="text" value=""/>

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" value=""/>
Other exemption - Write in:	<input type="text" value=""/>
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" value=""/>
If yes, attach documentation from FDA.	<input type="text" value=""/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.066	1.457	1.083	6.142	9.6916522	1
Case:	14.5	10	13	14	1820	48
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	1		00370700107164	
Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	48		10370700107161	
Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$70.00"/>	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:



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

Is this product regulated for shipment by DOT? 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 this product regulated for shipment by IATA? 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? 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:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- 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: 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	
Purchase orders may be accepted by:	
a. EDI	<input type="checkbox"/>
b. Autofax	<input type="checkbox"/>
c. Fax	<input type="checkbox"/>
d. Phone only	<input type="checkbox"/>
e. Supplier Web Site only	<input type="checkbox"/>
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"/>

Standard Order Receipt and Processing	
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:	
Expedited freight fees billed with each order:	<input type="checkbox"/>
Drop Ship service fee billed with each order:	<input type="checkbox"/>
Drop Ship miscellaneous fees billed:	<input type="checkbox"/>
Comments:	<input type="text"/>

Overnight and Priority Overnight PO Processing	
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="checkbox"/> Phone #: <input type="text"/> Fax: <input type="checkbox"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/>
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:	
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"/>

Return Instructions	
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:	
<input type="text"/>	

ADDITIONAL INFORMATION	
Is product order for scheduled patient procedure?	<input type="checkbox"/>
Is product order for restocking purposes?	<input type="checkbox"/>