



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

Version 2020

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	<input type="text" value="Xiromed LLC"/>	Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="213601"/>		
DUNS:	<input type="text" value="080228637"/>		
Proprietary Name (if Applicable) and Established Name:	<input type="text" value="KETOCONAZOLE"/>		
Selling Unit NDC:	<input type="text" value="70700-160-19"/>	Unit of Use NDC:	<input type="text" value=""/>
UDI	<input type="text" value=""/>	UPC:	<input type="text" value="370700160190"/>
	<input type="text" value=""/>	CVX Code:	<input type="text" value=""/>
	<input type="text" value=""/>	MXV Code:	<input type="text" value=""/>
Description:	<input type="text" value="Ketoconazole Foam, 2% 50g Can"/>		
Active Ingredient(s):	<input type="text" value="KETOCONAZOLE"/>		
URL for Additional Product Information:	<input type="text" value=""/>		
Address:	<input type="text" value="180 Park Ave"/>	Address 2:	<input type="text" value="Suite 101"/>
City:	<input type="text" value="Florham Park"/>	State:	<input type="text" value="NJ"/>
Key Contact:	<input type="text" value="Xiromed Regulatory"/>	Zip:	<input type="text" value="07932"/>
Phone Number:	<input type="text" value="844-947-6633"/>	Email:	<input type="text" value="usregulatory@xiromed.com"/>
		Fax:	<input type="text" value="862-286-0932"/>
Product Therapeutic Classification:	<input type="text" value=""/>		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	<input type="text" value="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="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>b. Contact for temperature excursion questions:</b>	
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"/>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
<b>e. Shelf life:</b>	<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="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="Yes"/>	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="No"/>	Size:	<input type="text" value="50g Can"/>
opioid?	<input type="text" value="No"/>	Strength:	<input type="text" value="2%"/>
Cannabinoid?	<input type="text" value="No"/>	Dosage Form:	<input type="text" value="AEROSOL, FOAM"/>
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	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Box containing 1 Canister"/>
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="32"/> 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="AT"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Exlina Foam, 2%"/>
<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 Box containing 1 Canister"/>	<input checked="" 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="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	Other exemption: (Write in) <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		
Item/Each:	0.882	1.575	1.575	5.512	13.673205	1
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	34.471	6.693	1.89	1.862	23.553872	32
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	<input type="text" value="1"/>	<input type="text" value=""/>	<input type="text" value="00370700160190"/>	<input type="text" value=""/>
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
<input checked="" type="checkbox"/> Case	<input type="text" value="32"/>	<input type="text" value=""/>	<input type="text" value="10370700160197"/>	<input type="text" value=""/>
<input type="checkbox"/> Pallet	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$472.24"/>	Whsl. Code #:	<input type="text" value=""/>
As of date:	<input type="text" value=""/>	Fineline Code:	<input type="text" value=""/>



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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?

Is this product regulated for shipment by DOT?  
 (if yes, answer a-e below and provide SDS)  Yes

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?  Yes

Is this product regulated for shipment by IATA?  
 (if yes, answer a-e below and provide SDS)  Yes

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?  Yes

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)

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?  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:

