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: Xiromed LLC | Application: ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 213601
DUNS: 080228637
Proprietary Name (If Applicable) and Established Name: KETOCONAZOLE
Selling Unit NDC: 70700-160-20 | Unit of Use NDC: | UPC: 370700160206
UDI: | CVX Code: | MVX Code:
Description: Ketoconazole Foam, 2% 100g Can
Active Ingredient(s): KETOCONAZOLE
URL for Additional Product Information:
Address: 180 Park Ave | Address 2: Suite 101
City: Florham Park | State: NJ | Zip: 07932
Key Contact: Xiromed Regulatory | Email: usregulatory@xiromed.com
Phone Number: 844-947-6633 | Fax: 862-286-0932
Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

The product is?
- a legend device? No
- if yes, enter class #
- a product kit? No
- if yes, list NDCs of component parts
- reverse numbered? No
- co-licensed? No
- latex-free? Yes
- preservative-free? Yes
- correctional institution block? Yes
- opioid? No
- Cannabinoid? No

If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose, indicate NDC here:

Is the Product… Direct-Ship Only
Is the Product… Neither
Orphan Drug Status
FDA Approval Status
Allergens Present: Not made with natural rubber latex.
Country of Origin: Spain
Is this product covered under the Trade Agreements Act (TAA)? Yes

PRODUCT DESCRIPTION INFORMATION

Size: 100g Can
Strength: 2%
Dosage Form: AEROSOL, FOAM
Product Shape:
Product Color:
Product Imprint:

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AT
II. Generic Equivalent to What Brand?: Extina Foam, 2%

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
Is product exempt from DSCSA? No
If yes, select exemption: Other exemption: (Write in)
Other exemption - Write in:
Is product repackaged? No
Is product sold by manufacturer's exclusive distributor? No
Has FDA granted waiver/exception/exemption for product? No

GLN: 0370700000007
If Yes, was original product purchased direct from mfr?
If yes, attach documentation from FDA.

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure		Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00370700160206	
	Box/Carton/Bundle/Inner Pack				
x	Case	32		10370700160203	
	Pallet				

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in):
Notes:
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No

b. Contact for temperature excursion questions:
Name: Xiromed Quality
Number: 844-947-6633
Group E-mail: US-Quality-Xiromed@xiromed.com

c. Special regulations for product in any states? No
Special returns requirements for this product? No

d. Store product (unit of sale) upright?
Protect product (unit of sale) from light? Yes

e. Shelf life: 24 Months
Initial shelf life at launch (if different): Months

ORDER INFORMATION

Unit of Sale:
- [ ] Bottle
- [x] Box/Carton
- [ ] Ampule
- [ ] Glass
- [ ] Tube
- [ ] Vial Liquid Sgl
- [ ] Vial Liquid Multi
- [ ] Vial Powder Sql
- [ ] Vial Power Multi
- [ ] Other: Write In

What is the NDC selling unit? 1 Box containing 1 Canister
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?
- 32 Each
- Inner/Carton/Pack
- Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer: 1 Box containing 1 Canister
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:
- [x] Each
- [ ] Gram
- [ ] Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	0.992	1.575	1.575	5.512	13.673205	1
Box/Carton/Bundle/ Inner Pack:					0	
Case:	34.586	6.693	1.89	1.862	23.553872	32
Pallet:					0	

COST INFORMATION

Regular Cost
Invoice Cost (WAC) ($): $552.66
As of date:

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

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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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?	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?	No
(If yes, attach SDS with special instructions.)	
e. Does the product contain DEHP?	
Is this product regulated for shipment by DOT?	Yes
(if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	1950
b. Proper Shipping Name	Aerosols, flammable
c. DOT Hazard Class	2.1
d. Packing Group	n/a
e. Inhalation Hazard?	Yes
Is this product regulated for shipment by IATA?	Yes
(if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	1950
b. Proper Shipping Name	Aerosols, flammable
c. DOT Hazard Class	2.1
d. Packing Group	n/a
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#

SDS Hazard Classification

- [ ] Organic
- [ ] Inorganic
- [ ] Steroid/Androgen
- [ ] Corrosive
- [ ] Oxidizer
- [ ] Contact Hazard
- [x] Aerosol Class; Identify NFPA Storage Level: Level 1

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics: D001

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

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:

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:

Release DATE

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Version 2020

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
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:
PO Receipt cut off time:
Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

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:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

Contact # if product is 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:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?