



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

☐ Final Version

Date: 8/30/2016

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: <input type="text"/> Amneal Pharmaceuticals Application: <input type="text"/> ANDA		a. Temperature – Indicate the USP temperature range for this product.	
Application Number for NDA/ANDA/BLA, Med Device: <input type="text"/>		<input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F)	
Rx Product/Proprietary Name: <input type="text"/> Yuvaferm (estradiol vaginal tablets, USP) 10mcg		<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)	
NDC: <input type="text"/> 65162-226-23 UPC: <input type="text"/> 3-6516222623-2		<input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F)	
CVX Code: <input type="text"/> MVX Code: <input type="text"/>		<input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)	
Description: <input type="text"/> White to off-white, round biconvex, film-coated unscored tablets debossed with "276" on obverse and "AN" on the reverse. Each Yuvaferm, estradiol vaginal tablet, 10 mcg is contained in a disposable, single-use applicator, packaged in a blister pack.		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)	
Active ingredients: <input type="text"/> Estradiol		<input type="checkbox"/> VI. Other Temperature Range Requirement (write in) <input type="text"/>	
URL for Additional Product Information: <input type="text"/>		<input type="checkbox"/> VII. No Requirement	
Address: <input type="text"/> 118 Beaver Trail Address 2: <input type="text"/>		b. Contact for temperature excursion questions:	
City: <input type="text"/> Glasgow State: <input type="text"/> KY Zip: <input type="text"/> 42141		Name: <input type="text"/>	
Key Contact: <input type="text"/> Email: <input type="text"/>		Number: <input type="text"/> 866-525-7270	
Phone Number: <input type="text"/> 866-525-7270 Fax: <input type="text"/> 866-525-7271		Is this product to be shipped to customers on ice? <input type="text"/> No	
		Is this product to be shipped to customers on dry ice? <input type="text"/> No	
FOR GENERIC DRUG PRODUCTS		c. Special regulations for product in certain states? <input type="text"/> No	
I. Orange Book Rating: <input type="text"/> AB II. Brand Name: <input type="text"/> Vagifem		Special returns requirements for this product? <input type="text"/> No	
III. Generic Equivalent for Brand: <input type="text"/> Yuvaferm (estradiol vaginal tablets, USP) 10mcg		d. Store product (unit of sale) upright? <input type="text"/> Yes	
		Protect product (unit of sale) from light? <input type="text"/> No	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		e. Shelf life: <input type="text"/> 24 Months	
Does supplier meet DSCSA definition of manufacturer? <input type="text"/> Yes DUNS: <input type="text"/> 831227777		Initial shelf life at launch (if different): <input type="text"/> Months	
Is product exempt from DSCSA? <input type="text"/> No			
If yes, select exemption: <input type="text"/>			
Other exemption - Write in: <input type="text"/>			
Is product repackaged? <input type="text"/> No If Yes, was original product purchased direct from mfr? <input type="text"/>			
Is product sold by manufacturer's exclusive distributor? <input type="text"/> No			
Are any waivers granted for product ID/barcode? <input type="text"/> No If yes, attach documentation from FDA <input type="text"/>			
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product... <input type="text"/> Direct Ship Item		Weight Lbs. <input type="text"/> 90.72gm Dimensions (US msmts.) <input type="text"/> 6" <input type="text"/> 1.5" <input type="text"/> 4.75" Volume (Cube) <input type="text"/> # Pieces: <input type="text"/>	
Legend Device? <input type="text"/> No		Item: <input type="text"/>	
State Control? <input type="text"/> No		Box/ Carton: <input type="text"/>	
ARCOS reportable? <input type="text"/> No		Case: <input type="text"/> 11.2 lbs <input type="text"/> 15.25" <input type="text"/> 12.5" <input type="text"/> 10.25" <input type="text"/> 44	
Co-Licensed? <input type="text"/> No		Pallet: <input type="text"/>	
Controlled Substance? <input type="text"/> No		UPC: <input type="text"/>	
Schedule No.? <input type="text"/> (incl. N for non-narcotic)		Case: <input type="text"/>	
Controlled Substance Code: <input type="text"/>		Carton: <input type="text"/>	
Hazardous Material/Cytotoxic Agent? <input type="text"/>			
Is Item... <input type="text"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>			
Is it reverse numbered? <input type="text"/>			
WHOLESALE USE ONLY:		COST INFORMATION	
Vendor #: <input type="text"/>		Regular Cost Per Unit of Sale (\$) <input type="text"/>	
Whsl. Code #: <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text"/>	
Fineline Code: <input type="text"/>		Federal Excise Tax Per Unit of Sale <input type="text"/>	
		As of date: <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:



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

☐

Carcinogen

☐

Reproductive Toxicant

☐

Both

☐

Warning appears on label

c. Contact Hazard?

d. Does this product require special clean-up instructions?

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT?

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?

(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#

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

☐

Passenger

☐

Cargo

☐

Passenger & Cargo

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Yes	Level	How?				GTIN-14	
			Item	2D	Linear	RFID		
If not, when?		Box/Cartron		2D		Linear	RFID	
Items aggregated to case?		Case	x	2D		Linear	RFID	50365162226237
		Pallet		2D		Linear	RFID	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

☐

Organic

☐

Antineoplastic

☐

Corrosive

☐

Inorganic

☐

Steroid/Androgen

☐

Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

866-525-7270

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?

Listed Chemical (List I or II) (Indicate or Write-in below):

☐

Ephedrine

☐

Pseudoephedrine

☐

Phenylpropanolamine

☐

Iodine (≥2.2%)

☐

Other:

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:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="text"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="text"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>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</p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p>REMS or Registry Restrictions</p> <p>REMS: <input type="text"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="text"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p> <p>Miscellaneous Notes:</p> <p><input type="text"/></p>