

Standard Pharmaceutical Product Information (Rx Product Only)

| © August 2014 Introduction Type: New Item | | | | | | | F | inal Version | | Date: | 8/30 | /2016 | |
|--|---|----------------------------------|---|--|--|--|--|---|-------------------------------|--|---|------------------|-----------------------------|
| | | Р | RODUCT INFORMATION | | | | | | SPECIAL HA | NDLING AND S | TORAGE REQU | JIREMENTS* | |
| Company Name: Amneal Pharmaceuticals | | | | | Application: | AND | A | a. Temperatur | e – Indicate th | e USP tempera | ture range for | this product. | |
| Application Number fo | or NDA/ANDA/BLA, Me | ed Device: | | <u> </u> | •• | | | I. | Freezer – betw | een -25 and -10 | O C (-13° – 14° F | ·) | |
| Rx Product/Proprietary N | Name: | Yuvafem (estra | diol vaginal tablets, USP) 1 | 10mcg | | | | | . Cold – betwee | en 2 and 8 C (36 | 6° – 46° F) | | |
| NDC: | 65162-226-23 | , | | UPC: | 3-6516222623-2 | | | | | en 8 and 15 C (4 | , | | |
| CVX Code: | | | | MVX Code: | | | | x I\ | V. Controlled Ro | om – between | 20 and 25 C (68 | ° – 77° F) | |
| Description: White to off-white, round biconvex, filr | | | n-coated unscored tablets debossed with "276" on obverse and "AN" on the reverse. Each | | | | e. Each | allows for excursions between 15 and 30 C (59° – 86° F) | | | | | |
| | | | ncg is contained in a disposable, single-use applicator, packaged in a blister pack. | | | | | V. Avoid Excessive Heat – above 40 C (>104° F) | | | | | |
| Active ingredients: Estradiol | | | | | | | VI. Other Temperature Range Requirement | | | | | | |
| | | | | | | | | (write in) | | | | | |
| URL for Additional Product Information: | | | | | | | | VII. No Requirement | | | | | |
| Address: | 118 Beaver Trail | | | Address 2: | | Linia | | b. Contact for | temperature e | xcursion ques | tions: | | |
| City: | Glagow | | State: KY Zip: 42141 | | | | Name: | | | | | | |
| Key Contact: Phone Number: | 866-525-7270 | | Fax: | 866-525-7271 | 1 | | | Number: 866-525-7270 Is this product to be shipped to customers on ice? No | | | | | |
| Thore Number. | 000 020 7270 | FOR | GENERIC DRUG PRODU | | | | | | | d to customers of | | | - |
| | | FUR | _ | | | | | io tillo produ | iot to be omppet | a to ouotomero t | on ary loo. | No | - |
| I. Orange Book Rating: | AB | | II. Brand Name: | Vagifem | | | | | | | 4-40 | NI- | |
| III. Generic Equivalent fo | | | diol vaginal tablets, USP) 1 | | | | | | • | oduct in certai | | No | - |
| | DRU | IG SUPPLY CHA | AIN SECURITY ACT (DSCSA) INFORMATION | | | | | Special retur | rns requirement | s for this produc | ct? | No | <u>-</u> |
| Does supplier meet DSC | SA definition of manu | facturer? | Yes | DUNS: | 831227777 | | | | | | | | |
| Is product exempt from I | DSCSA? | No | _ | | | | | d. Store prod | uct (unit of sal | e) upright? | | Yes | _ |
| If yes, select exemption | on: | | | | | | | Protect pro | oduct (unit of s | ale) from light | ? | No | |
| Other exemption - Wri | te in: | | | | | | | | | | | | - ' |
| Is product repackaged? | | No | If Yes, was original product purchased direct from mfr? | | | | | e. Shelf life: | 24 | Months | | | |
| Is product sold by manu | facturer's exclusive d | -4-1 | | | | | | | | | | | |
| Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA | | | | | | | | | | fe at launch (if | different): | | Months |
| Are any waivers granted | | | No No | If yes, attach | documentation from | n FDA | | | Initial shelf li | ife at launch (if | different): | | Months |
| Are any waivers granted | | le? | | | documentation fron | n FDA | | | | ife at launch (if | , | | Months |
| Are any waivers granted Is the Product | | le? | No | | | n FDA | | Weight Lbc | ITEM AND | , | ORMATION | Volume | |
| Is the Product Legend Device? | for product ID/barcoo | ADDITIONAL F | No PRODUCT INFORMATION Unit of Sale | ORDER INFOR | RMATION NDC selling unit? | | | Weight Lbs. | ITEM AND | PACKING INF | ORMATION | Volume (Cube) | Months # Pieces: |
| Is the Product Legend Device? State Control? | for product ID/barcoo | ADDITIONAL F No No | No PRODUCT INFORMATION Unit of Sale Bottle | ORDER INFORMATION What is the North 18 disposable | RMATION NDC selling unit? e, single-use applicator | | Item: | Weight Lbs. | ITEM AND | PACKING INF | FORMATION nsmts.) | | |
| Is the Product Legend Device? State Control? ARCOS reportable? | for product ID/barcoo | ADDITIONAL F No No No | No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton | ORDER INFORMATION What is the Market 18 disposable in a blister page | RMATION NDC selling unit? e, single-use applicator ck | | | | ITEM AND Dim Depth | PACKING INF nensions (US n Height | FORMATION Insmts.) Width: | | |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? | for product ID/barcoo | NO NO NO | No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule | ORDER INFORMATION What is the Market 18 disposable in a blister page | RMATION NDC selling unit? e, single-use applicator | | Box/ | | ITEM AND Dim Depth | PACKING INF nensions (US n Height | FORMATION Insmts.) Width: | | |
| Is the Product Legend Device? State Control? ARCOS reportable? | for product ID/barcoo | ADDITIONAL F No No No | No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton | ORDER INFORMATION What is the Market 18 disposable in a blister page | RMATION NDC selling unit? a, single-use applicatock thick In 1 Box of 10 Vials) | | Box/ Carton: | 90.72gm | Dim Depth | PACKING INF nensions (US n Height | FORMATION msmts.) Width: 4.75" | | # Pieces: |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? | Direct Ship Item | NO NO NO | No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass | ORDER INFOR What is the N 18 disposable in a blister par (Write-in, e.g | RMATION NDC selling unit? a, single-use applicatock thick In 1 Box of 10 Vials) | r, packaged | Box/ | | ITEM AND Dim Depth | PACKING INF nensions (US n Height | FORMATION Insmts.) Width: | | |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co | Direct Ship Item Direct Ship Item | NO NO NO | No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi | ORDER INFORMATION ORDER INFORM | RMATION NDC selling unit? e, single-use applicatock i. 1 Box of 10 Vials) der quantity? nany of which packa | r, packaged Yes | Box/ Carton: Case: | 90.72gm | Dim Depth | PACKING INF nensions (US n Height | FORMATION msmts.) Width: 4.75" | | # Pieces: |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot | Direct Ship Item Direct Ship Item | NO NO NO | No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql | ORDER INFOR What is the N 18 disposable in a blister par (Write-in, e.g | RMATION NDC selling unit? a, single-use applicatock 1 1 Box of 10 Vials) Her quantity? The package of the pack | Yes age type? | Box/ Carton: | 90.72gm 11.2 lbs | Dim Depth | PACKING INF nensions (US n Height | FORMATION msmts.) Width: 4.75" | | # Pieces: |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cc Hazardous Material/Cyto | Direct Ship Item Direct Ship Item | NO NO NO | No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi | ORDER INFORMATION ORDER INFORM | RMATION NDC selling unit? a, single-use applicatock a. 1 Box of 10 Vials) der quantity? nany of which packate Each Inner/Carton/Pack | Yes age type? | Box/ Carton: Case: | 90.72gm 11.2 lbs | Dim Depth | PACKING INF nensions (US n Height | FORMATION msmts.) Width: 4.75" | | # Pieces: |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cc Hazardous Material/Cyto | Direct Ship Item Direct Ship Item ic) ode: otoxic Agent? | NO NO NO | No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql | ORDER INFORMATION ORDER INFORM | RMATION NDC selling unit? a, single-use applicatock 1 1 Box of 10 Vials) Her quantity? The package of the pack | Yes age type? | Box/ Carton: Case: Pallet: | 90.72gm 11.2 lbs | Dim Depth | PACKING INF nensions (US n Height | FORMATION msmts.) Width: 4.75" | | # Pieces: |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co | Direct Ship Item Direct Ship Item ic) ode: otoxic Agent? | NO NO NO | No PRODUCT 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 | ORDER INFOR What is the N 18 disposable in a blister par (Write-in, e.g Minimum ord If Yes, how n 44 | RMATION NDC selling unit? a, single-use applicatock a. 1 Box of 10 Vials) der quantity? nany of which packate Each Inner/Carton/Pack Case | Yesage type? | Box/ Carton: Case: Pallet: UPC: | 90.72gm 11.2 lbs | Dim Depth | D PACKING INF nensions (US n Height 1.5" | FORMATION Insmts.) Width: 4.75" 10.25" | | # Pieces: |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co hospital scanning? | Direct Ship Item Direct Ship Item ic) ode: otoxic Agent? | NO NO NO | No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi | ORDER INFOR What is the N 18 disposable in a blister pac (Write-in, e.g Minimum ord If Yes, how n 44 / BILL UNIT | RMATION NDC selling unit? a, single-use applicator ck a. 1 Box of 10 Vials) der quantity? nany of which packate Each Inner/Carton/Pack Case Other Pro | Yesage type? | Box/ Carton: Case: Pallet: UPC: | 90.72gm 11.2 lbs Case: Carton: | Dim Depth 6" 15.25" | PACKING INFORMATION (US not Height 1.5" 12.5" | FORMATION Insmts.) Width: 4.75" 10.25" | (Cube) | # Pieces: |
| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto Is Item If Unit Dose, is item bar co | Direct Ship Item Direct Ship Item ic) ode: otoxic Agent? | NO NO NO | No PRODUCT 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 | ORDER INFOR What is the N 18 disposable in a blister pac (Write-in, e.g Minimum ord If Yes, how n 44 / BILL UNIT | RMATION NDC selling unit? a, single-use applicatock a. 1 Box of 10 Vials) der quantity? nany of which packate Each Inner/Carton/Pack Case | Yes age type? | Box/ Carton: Case: Pallet: UPC: | 90.72gm 11.2 lbs Case: Carton: | Dim Depth | PACKING INFORMATION (US not Height 1.5" 12.5" | FORMATION Insmts.) Width: 4.75" 10.25" | (Cube) | # Pieces: |
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| Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cc Hazardous Material/Cyto Is Item If Unit Dose, is item bar cohospital scanning? Is it reverse numbered? | Direct Ship Item Direct Ship Item ic) ode: otoxic Agent? | NO NO NO | No PRODUCT 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 PHARMACY ORDER Rec. sell unit to custon | ORDER INFOR What is the N 18 disposable in a blister par (Write-in, e.g Minimum ord If Yes, how n 44 / BILL UNIT ner? | RMATION NDC selling unit? a, single-use applicato ck 1 Box of 10 Vials) der quantity? nany of which packate Each Inner/Carton/Pack Case Other Prof Size/Strength/For 18 single-use application Product Shape: | Yes Age type? Oduct Information Cators; 10mcg; T round, biconve | Box/Carton: Case: Pallet: UPC: Gablet | 90.72gm 11.2 lbs Case: Carton: | Dim Depth 6" 15.25" | PACKING INFORMATION (US not Height 1.5" 12.5" | FORMATION Insmts.) Width: 4.75" 10.25" | (Cube) | # Pieces: 44 cise Tax Per |
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIA | L HAZARD CLASSIFICATION and TRANSPORTATION | N Comment of the Comm |
|--|---|--|
| 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 | Hazardous Waste | Identification |
| c. Contact Hazard? | EPA Hazardous Waste Code: | |
| d. Does this product require special clean-up instructions? | <u> </u> | |
| (If yes, attach SDS with special instructions.) | | |
| e. Does the product contain DEHP? | | |
| Is this product regulated for shipment by the DOT? | (if yes, answer a-d below and provide SDS) a. DOT Hazard Class | |
| Is this a reportable quantity? | b. UN/ID Number | |
| RQ Threshold: | c. Packing Group | |
| Is this a marine pollutant? | d. Inhalation Hazard? | |
| Is this a mainle politicant: Is this product shipped utilizing an authorized DOT exception or Special Permit? | d. Illialation Hazard: | |
| (if yes, identify method below) | | |
| | | |
| Limited Quantity | ADDITIONAL | PRODUCT INFORMATION - Serialization |
| Consumer Commodity, ORM-D | | Level How? GTIN-14 |
| Small Quantity (49 CFR 173.4) | Serialized? Yes | Item 2D Linear RFID |
| Special Permit; DOT-SP | If not, when? | Box/Carton 2D Linear RFID |
| Special Provision (listed in Column 7 of 49 CFR 172.101); | Items aggregated to case?x | |
| SP# | | Pallet 2D Linear RFID |
| Is the product restricted for air shipment? If so, indicate restriction: | REMS | S or REGISTRY RESTRICTIONS |
| Passenger Cargo | Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? | No No |
| Passenger & Cargo | Website URL: | |
| ADD'L STORAGE INFORMATION | | 2) |
| | Comments / Details: (For example, iPledge program | <u>()</u> |
| Please check as appropriate for this product. Organic Inorganic Antineoplastic Steroid/Androgen Corrosive Oxidizer | | |
| Aerosol Class; Identify NFPA Storage Level: | | RETURN INSTRUCTIONS |
| | Contact tel. # if product received damaged: | 866-525-7270 |
| | Is product returnable for credit: | |
| Listed Chemical (List I or II) (Indicate or Write-in below): | URL/Link to returns policy: | |
| Ephedrine | Special regulations or returns requirements for this pr | roduct in certain states? |
| Pseudoephedrine | If so, which states? Other requirements? Comments? | ? |
| Phenylpropanolamine | | |
| Iodine (≥2.2%) | | |
| Other: | | |
| CLASS OF TRADE RESTRICTION: | Į. | ADDITIONAL INFORMATION |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | If Unit Dose NDC, indicate NDC here: | |
| Restricted to retail pharmacy only: | MISCELLANEOU | IS NOTES and/or Image of Product Barcode: |
| | | |
| Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) | | |
| | | |
| | | |
| Comments: | | |
| | | |
| | | |



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