

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

| Version 2021  |  |                      |                                      |               |                 | Introduction 1              | Туре:        | Open Stock  | 1   | Final Version  |                              |                           | Date:                               | 7/13/         | /2023            |
|---|--|----------------------|--------------------------------------|---------------|-----------------|-----------------------------|--------------|---|---|--|------------------------------|---------------------------|-------------------------------------|---------------|------------------|
|   |  |                      | PRODUCT INFORMA                      | TION          |                 |                             |              |   |   | SPECIAL  | HANDLING AND STO             | RAGE REQUI                | REMENTS*                            |               |                  |
| Company Name: Xiromed LLC Application   |  |                      |                                      |               |                 | tion:                       | ANDA         | a. Temperature – Indicate the USP temperature range for this product. |   |  |                              |                           |                                     |               |                  |
|   | ANDA/BLA (drug); PMA/510(k)(med device): 091232  |                      |                                      |               |                 |                             |              | Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) |   |  |                              |                           |                                     |               |                  |
| Medical Device Class, if applical   | ble:   |                      |                                      |               |                 |                             |              |   |   |  | 1                            |                           |                                     |               |                  |
| DUNS:   | 080228637  |                      |                                      |               |                 |                             |              |   |   | Other Temperature Ra                                 | nge Requirement              |                           |                                     |               |                  |
| Proprietary Name (If Applicable) a  |  | ame: Tri-L           | o-Estarylla                          |               | 1               | 1100                        | 0707004      | 100050  |   | (write in)   |                              |                           |                                     |               |                  |
| Selling Unit NDC:<br>UDI  | 70700-120-85   |                      | Unit of Use NDC:<br>CVX Code:        |               |                 | UPC:<br>MVX Code:           | 3707001      | 120859  |   | Notes  |                              |                           |                                     |               |                  |
| -   | Nerrestimete : E   | C 0 10/0 215/0 25    |                                      |               |                 |                             |              |   | 1   | la this was duet to be al                            |                              | 1002                      |                                     | No            | 1                |
| Description: Norgestimate + EE, 0.18/0.215/0.25-0.025mg - 3 x 28 Pack Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No |  |                      |                                      |               |                 |                             |              |   |   |  |                              |                           |                                     |               |                  |
| Active Ingredient(s): Norgestimate And Ethinyl Estradiol  |  |                      |                                      |               |                 |                             |              |   |   |  |                              |                           |                                     |               |                  |
|   |  |                      |                                      |               |                 |                             |              |   | b. Contact for temperature excursion questions:<br>Name: VIPUL GANDHI |  |                              |                           |                                     |               |                  |
| URL for Additional Product Inform<br>Address:   |  |                      |                                      |               |                 | Address 2:                  | Suite 10     | 14  |   |  |                              |                           | 73-953-7867                         |               |                  |
| City:   |  |                      |                                      |               | NJ              | Zip:                        |              |   |   |  |                              | PUL.GANDHI@XIROMED.COM;   |                                     |               |                  |
| Key Contact:  |  |                      |                                      |               | david.hernandez |                             |              |   |   |  |                              |                           | 4                                   |               |                  |
| Phone Number:   | 973-324-0200   | 73-324-0200 Fax: 862 |                                      |               |                 | 862-286-0932                | 862-286-0932 |   |   | c. Special regulations for product in any states? No |                              |                           |                                     | ]             |                  |
| Product Therapeutic Classificatio   | n:   | Combination Oral     | Contraceptive                        |               |                 |                             |              |   |   | Special returns require                              | ments for this product       | ?                         |                                     | No            |                  |
|   |  |                      |                                      |               |                 | PRODUCT                     | PEOODID      |   |   |  |                              |                           |                                     |               | 1                |
|   | ADDITI   | ONAL PRODUCT         |                                      |               |                 | PRODUCT                     | DESCRIP      | TION INFORMATION  | d. Store produ  | ict (unit of sale) uprig                             |                              |                           |                                     | Yes           | 1                |
| The product is?   |  |                      | Is the Product                       | Direct-Ship C | Only            |                             | 0            | 00 De els   | o ob alt liter  | Protect product (unit                                | of sale) from light?         |                           |                                     | Yes           |                  |
| a legend device?<br>if yes, enter class #   |  | No                   | Is the Product<br>Orphan Drug Status | Neither       |                 | Size:                       | 3            | x 28 Pack   | e. Shelf life:  | Initial shelf life at lau                            | nch (if different):          |                           |                                     | 24            | Months<br>Months |
| a product kit?  |  |                      | Orphan Drug Status                   |               |                 |                             | 0            | ).18mg/0.215mg/0.25mg-0   |   | initial shen hie at lau                              | ien (in unterent).           |                           |                                     |               | WOITINS          |
| if yes, list NDCs of  |  |                      | FDA Approval Status                  |               |                 | Strength:                   |              |   |   |  | ORDER INFOR                  | MATION                    |                                     |               |                  |
| component parts   |  |                      |                                      |               |                 | Dosage Form                 | m: T         | ablets  |   |  |                              |                           |                                     |               |                  |
| reverse numbered?   |  | No                   | <u>.</u> .                           |               |                 |                             |              |   |   | Unit of Sale   |                              |                           | NDC selling                         |               |                  |
| co-licensed?<br>latex-free?   |  | No                   | Allergens Present                    |               |                 |                             | P            | Round   |   | Bottle<br>X Box/Carton                               |                              |                           | , 3 blisters of :<br>.g. 1 Box of 1 |               |                  |
| preservative-free?  |  |                      |                                      |               |                 | Product Sha                 | ape:         | tound   |   | Ampule   |                              | (*******************      | .g. 1 Dox of 1                      | 0 1013)       |                  |
| correctional institution block?   |  |                      |                                      |               |                 | Product Col                 | 7            | white active; 7 light blue  |   | Glass  |                              | Minimum o                 | rder quantity                       | ?             | Yes              |
| opioid?   |  |                      |                                      | -             |                 | Flourer Con                 |              |   |   | Tube   |                              |                           |                                     |               |                  |
| Cannabinoid?  |  |                      | Country of Origin                    | Spain         |                 | Product Imp                 | orint: 7     | active SZ and T5; 7 activ   |   | Vial Liquid S  |                              |                           |                                     |               |                  |
| If Unit Dose, is item bar coded to u<br>hospital scanning?  | unit dose for  |                      | Is this product covered u            | under the     |                 |                             |              |   |   | Vial Liquid N<br>Vial Powder                         |                              |                           | many of whi<br>Each                 | ich package i | type?            |
| If Unit Dose, indicate NDC here:  |  |                      | Trade Agreements Act (               |               | Yes             |                             |              |   |   | Vial Power N   |                              | 00                        | Inner/Carton                        | /Pack         |                  |
|   |  |                      |                                      |               |                 |                             |              |   |   | Other: Write   | In                           |                           | Case                                |               |                  |
|   |  |                      | FOR GENERIC DRUG PR                  | ODUCTS        |                 |                             |              |   |   |  |                              |                           |                                     |               |                  |
|   |  |                      |                                      |               |                 |                             | *16 A        |   |   |  | PHARMACY ORDE                |                           |                                     |               |                  |
|   | 10   |                      |                                      |               | AL              | uthorized Generic           |              | orized Generic, other<br>fields are not applicable                    |   |  | PHARMACTORDE                 |                           |                                     |               |                  |
| I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Ortho Tri-Cyclen Lo  |  |                      |                                      |               |                 |                             |              | Rec. sell unit to customer?   |   |  | Rx billing unit to pharmacy: |                           |                                     |               |                  |
| ii. Generic Equivalent to What Brand?.  |  |                      |                                      |               |                 |                             |              | (Write-in, e.g. 1 Vial) Gram  |   |  |                              |                           |                                     |               |                  |
|   |  | DRUG SUP             | PLY CHAIN SECURITY ACT (             | (DSCSA) INFOR | RMATION         |                             |              |   |   |  |                              |                           | Milliliter                          |               |                  |
|   |  |                      | Yes                                  | _             | 01.11           | 0370700000007               |              |   |   |  | ITEM AND PACKING             |                           | N                                   |               |                  |
| Does supplier meet DSCSA defini<br>Is product exempt from DSCSA?  | tion of manufactu  |                      | No                                   | -             | GLN:            | 0370700000007               |              |   |   |  | ITEM AND FACKING             |                           | N                                   |               |                  |
| If yes, select exemption:   |  |                      |                                      |               | GCP:            |                             |              |   |   |  | Dimen                        | sions (US msr             | nts.)                               | Volume        | Saleable #       |
| Other exemption - Write in:   |  |                      |                                      |               |                 |                             |              |   |   | Weight L   | os. Depth                    | Width                     | Height                              | (Cube)        | Pieces           |
| Is product repackaged?  |  |                      | No                                   |               |                 | riginal product pur         | chased       |   | Item/Each:  | 0.08   | 4.0                          | 2.0                       | 1.0                                 | 8.0           | 1                |
| Is product sold by manufacturer's<br>Has FDA granted waiver/exception   |  |                      | No<br>No                             |               | direct from n   | ntr?<br>rce manufacturer fo | or ronooka   | aged product  | Box/Carton/Bi   | undlo/   |                              |                           |                                     |               |                  |
| If yes, attach documentation from   |  |                      |                                      |               | FIOVICE SOUL    | ce manufacturer ic          | ог тераска   | aged product  | Inner Pack:   |  |                              |                           |                                     | 0             |                  |
|   |  |                      |                                      |               |                 |                             |              |   | Case:   | 6.9  | 10.7                         | 8.4                       | 8.5                                 | 763.98        | 80               |
|   |  | G                    | TIN AND HIBCC PRODUCT I              | NFORMATION    |                 |                             |              |   |   | 0.5  | 10.7                         | 0.4                       | 0.0                                 | 100.00        | 00               |
| Saleable Unit of Measure  | c  | Saleable Quantity    | HIBCC                                |               | GTI             | IN-14                       |              | Unit of Use GTIN-14   | Pallet:   |  |                              |                           |                                     | 0             |                  |
| x Item/Each   |  | 1                    | TIBOO                                |               |                 | 370700120859                |              | 01111 01 036 01114-14   |   |  |                              |                           |                                     |               |                  |
| Box/Carton/Bundle/Inner Pack  |  |                      |                                      |               |                 |                             | - ·          |   |   | COST INFORMAT  | ION                          |                           | WHOLESAL                            | ER USE ONL    | .Y:              |
| X Case  |  | 80                   |                                      |               | 203             | 370700120853                |              |   |   |  |                              |                           |                                     |               |                  |
| Pallet  |  |                      |                                      |               | _               |                             | -            |   | Regular Cost  |  |                              | Vendor #:                 |                                     |               |                  |
|   | -  |                      |                                      |               |                 |                             | -            |   | Invoice Cost (  | WAC) (\$)  |                              | Whsl. Code<br>Fineline Co |                                     |               |                  |
|   | -  |                      |                                      |               |                 |                             | -            |   | As of date:   |  |                              | in menne Co               |                                     |               |                  |
|   |  |                      |                                      |               |                 |                             |              |   |   |  |                              |                           |                                     |               |                  |
|   |  |                      |                                      |               |                 |                             |              |   |   |  |                              |                           |                                     |               |                  |
|   |  |                      | Attach copy of SAFETY DA             | ATA SHEET (SD | S) or non haza  |                             |              | , LABEL AND PHOTO OF F  |   |  |                              |                           |                                     |               |                  |
| *Please provide any additional inf  | *Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature: |                      |                                      |               |                 |                             |              |   |   |  |                              |                           |                                     |               |                  |

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

| Version 2021 For Design  | ated Drop Ship Only Products, Please Use Page 3  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|
| MATERIAL HA  | AZARD 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? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No   | SDS Hazard Classification         Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard   |  |  |  |  |  |  |
| 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  | Does the product have an Aerosol class? If yes,<br>identify NFPA Storage Level:<br>NFPA Storage Level:<br>Is the product a NIOSH hazardous drug?<br>Yes  |  |  |  |  |  |  |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group  | If yes, indicate which:<br>Group 2 items (non-antineoplastic that meets a hazard criterion)<br>Hazardous Waste Identification  |  |  |  |  |  |  |
| e. Inhalation Hazard? No   | EPA Hazardous Waste Code: Waste Characteristics  |  |  |  |  |  |  |
| 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   | REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         If Yes, is it managed with a pharmacy registry?       Website URL:   |  |  |  |  |  |  |
| e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo   | Med Guide Required       Limited Distribution Requirement       Comments / Details: (For example, iPledge program?)  |  |  |  |  |  |  |
| Is this a reportable quantity? No<br>RQ Threshold:<br>Is this a marine pollutant? No<br>Is this product shipped utilizing an authorized DOT exception or Special Permit?<br>No (if yes, identify method below)<br>Limited Quantity<br>Consumer Commodity, ORM-D<br>Small Quantity (49 CFR 173.4)<br>Special Permit; DOT-SP<br>Special Perovision (listed in Column 7 of 49 CFR 172.101); | REMS:     Phone:       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Site Enrollment Number assigned     DEA #:       by Supplier:     NPI #: |  |  |  |  |  |  |
| Special Provision (listed in Column 7 of 49 CFR 172, 101);<br>SP#  | Registry:  |  |  |  |  |  |  |
| ADD'L STORAGE INFORMATION Is the Product   | Registry Program Contact Name: Phone: Phone: Comments  |  |  |  |  |  |  |
| 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  | RETURN INSTRUCTIONS         Contact tel. # if product received damaged:         Is product returnable for credit:  |  |  |  |  |  |  |
| CLASS OF TRADE RESTRICTION:  | URL/Link to returns policy:  |  |  |  |  |  |  |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices       Yes         Restricted to retail pharmacy only:  | Special regulations or returns requirements for this product in certain states?<br>If so, which states? Other requirements? Comments?  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| MISCELLAN  | EOUS NOTES and/or Image of Product Barcode:  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |



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

| Version 2021 FOR DESIGNATED DROP SHIP PRODUCT ONLY - i   | 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:         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: | 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:  | Overnight and Priority Overnight PO Processing  |
| Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:  | Overnight receipt available:       Image: Comparison of the second |
| Class of Trade Restriction:  | PO Receipt Cut off time:  |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices<br>Restricted to retail pharmacy only:<br>Restricted to hospital, clinics, and physician offices only:<br>Restricted from US territories? (explain in comments)<br>Comments:   | Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       Fax #:         EDI:         Other fees apply:  |
| Other Data Information Required to Process PO:   | Return Instructions   |
| Patient Procedure Date:  | Contact # if product is received damaged:<br>Is product returnable for credit:<br>URL/Link to returns policy:<br>Special regulations or returns requirements for this product in certain states?<br>If so, which states? Other requirements? Comments?  |
| Miscellaneous Notes:   |   |
|  | ADDITIONAL INFORMATION  Is product order for scheduled patient procedure? Is product order for restocking purposes?   |