



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

Version 2021 Introduction Type: [ ] Final Version Date: [ ]

| PRODUCT INFORMATION   |                                       |
|---|---------------------------------------|
| Company Name:   | XIROMED LLC                           |
| Application:  | ANDA                                  |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 215351                                |
| Medical Device Class, if applicable:                                |                                       |
| DUNS:   | 080228637                             |
| Proprietary Name (If Applicable) and Established Name:              | TESTOSTERONE CYPIONATE INJECTION, USP |
| Selling Unit NDC:   | 70700-290-22                          |
| Unit of Use NDC:  |                                       |
| UDI   |                                       |
| CVX Code:   |                                       |
| UFC:  |                                       |
| MVX Code:   |                                       |
| Description:  | TESTOSTERONE CYPIONATE INJECTION, USP |
| Active Ingredient(s):   | TESTOSTERONE CYPIONATE, USP           |
| URL for Additional Product Information:                             |                                       |
| Address:  | 180 PARK AVE                          |
| City:   | FLORHAM PARK                          |
| Key Contact:  | Xiromed Regulatory                    |
| Phone Number:   | 844-947-6633                          |
| Product Therapeutic Classification:                                 |                                       |
| Address 2:  | #101                                  |
| State:  | NJ                                    |
| Zip:  | 07932                                 |
| Email:  | usregulatory@xiromed.com              |
| Fax:  | 862-286-0932                          |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS*                                   |   |
|--|---|
| <b>a. Temperature – Indicate the USP temperature range for this product.</b> |   |
| Temperature Range  | Controlled Room – between 20 and 25 C (68° – 77° F) |
| Other Temperature Range Requirement (write in)                               | NO  |
| 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>b. Contact for temperature excursion questions:</b>                       |   |
| Name:  | Xiromed Quality                                     |
| Number:  | 973-953-7867  |
| Group E-mail:  | US-Quality-Xiromed@xiromed.com                      |
| <b>c. Special regulations for product in any states?</b>                     |   |
| Special returns requirements for this product?                               | No  |
| <b>d. Store product (unit of sale) upright?</b>                              |   |
| Protect product (unit of sale) from light?                                   | Yes   |
| <b>e. Shelf life:</b>  |   |
| Initial shelf life at launch (if different):                                 | 24 Months   |

| ADDITIONAL PRODUCT INFORMATION                                      |     | PRODUCT DESCRIPTION INFORMATION                               |                           |
|---|-----|---|---------------------------|
| The product is?   |     | Is the Product... Direct-Ship Only                            |                           |
| a legend device?  | No  | Is the Product... Neither                                     |                           |
| if yes, enter class #   |     | Orphan Drug Status  |                           |
| a product kit?  | No  | FDA Approval Status   |                           |
| if yes, list NDCs of component parts reverse numbered?              |     | Allergens Present   |                           |
| co-licensed?  | No  | oppers are not manufactured with natural rubber               |                           |
| latex-free?   | Yes | Country of Origin   | SPAIN                     |
| preservative-free?  | No  | Is this product covered under the Trade Agreements Act (TAA)? | Yes                       |
| correctional institution block?                                     | No  |   |                           |
| opioid?   | No  |   |                           |
| Cannabinoid?  | No  |   |                           |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? |     |   |                           |
| If Unit Dose, indicate NDC here:                                    |     |   |                           |
|   |     | Size:   | 10 mL multi dose          |
|   |     | Strength:   | 2000 mg/10 mL (200 mg/mL) |
|   |     | Dosage Form:  | INJECTABLE                |
|   |     | Product Shape:  |                           |
|   |     | Product Color:  |                           |
|   |     | Product Imprint:  |                           |

| ORDER INFORMATION                          |  |
|--|--|
| Unit of Sale                               | What is the NDC selling unit?                |
| <input checked="" type="checkbox"/> Bottle | Single Vial in Carton                        |
| <input type="checkbox"/> Box/Carton        | (Write-in, e.g. 1 Box of 10 Vials)           |
| <input type="checkbox"/> Ampule            |  |
| <input type="checkbox"/> Glass             | Minimum order quantity?                      |
| <input type="checkbox"/> Tube              | Yes  |
| <input type="checkbox"/> Vial Liquid Sgl   |  |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type?      |
| <input type="checkbox"/> Vial Powder Sgl   | <input checked="" type="checkbox"/> Each     |
| <input type="checkbox"/> Vial Power Multi  | <input type="checkbox"/> Inner/ Carton/ Pack |
| <input type="checkbox"/> Other: Write In   | <input type="checkbox"/> Case                |

| FOR GENERIC DRUG PRODUCTS              |   |
|--|---|
| I. Orange Book Rating:                 | AO  |
| II. Generic Equivalent to What Brand?: | DEPO-TESTOSTERONE   |
|  | <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:             |
| Single Vial in Carton       | <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?     | Yes          |
| Is product exempt from DSCSA?                            | No           |
| If yes, select exemption:                                |              |
| 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           |
| If yes, attach documentation from FDA.                   |              |
| GLN:   | 370700000007 |
| GCP:   |              |
| If yes, was original product purchased direct from mfr?  |              |
| Provide source manufacturer for repackaged product       |              |

| ITEM AND PACKING INFORMATION  |             |                        |       |        |               |                   |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|                               |             | Depth                  | Width | Height |               |                   |
| Box/Carton/Bundle/Inner Pack: |             |                        |       |        | 0             |                   |
| Case:                         |             |                        |       |        | 0             |                   |
| Pallet:                       |             |                        |       |        | 0             |                   |

| GTIN AND HIBCC PRODUCT INFORMATION                    |                   |       |                |                     |
|---|-------------------|-------|----------------|---------------------|
| Saleable Unit of Measure                              | Saleable Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
| <input checked="" type="checkbox"/> Item/Each         | 1                 |       | 00370700290224 |                     |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |                |                     |
| <input checked="" type="checkbox"/> Case              | 40                |       | 10370700290221 |                     |
| <input type="checkbox"/> Pallet                       |                   |       |                |                     |

| COST INFORMATION        |  | WHOLESALE USE ONLY: |  |
|-------------------------|--|---------------------|--|
| Regular Cost            |  | Vendor #:           |  |
| Invoice Cost (WAC) (\$) |  | Whsl. Code #:       |  |
| As of date:             |  | Fineline Code:      |  |

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For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION   |  |   |  |
|---|--|---|--|
| <p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?<br/>           Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No<br/>           Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No<br/>           Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?<br/>           (If yes, attach SDS with special instructions.) <input type="checkbox"/> Yes</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?<br/>           (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA?<br/>           (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger<br/> <input type="checkbox"/> Cargo<br/> <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No<br/>           RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?<br/> <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity<br/> <input type="checkbox"/> Consumer Commodity, ORM-D<br/> <input type="checkbox"/> Small Quantity (49 CFR 173.4)<br/> <input type="checkbox"/> Special Permit; DOT-SP<br/> <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);<br/>           SP# <input type="text"/></p> |  |   |  |
| <p><b>SDS Hazard Classification</b></p> <p><input type="checkbox"/> Organic<br/> <input type="checkbox"/> Inorganic<br/> <input type="checkbox"/> Steroid/Androgen</p> <p><input type="checkbox"/> Corrosive<br/> <input type="checkbox"/> Oxidizer<br/> <input type="checkbox"/> Contact Hazard</p> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/></p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No<br/>           If yes, indicate which: <input type="text"/></p>   |  | <p><b>Hazardous Waste Identification</b></p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics <input type="text"/></p> |  |
| <p style="text-align: center;"><b>REMS or REGISTRY RESTRICTIONS</b></p> <p>Is there a REMS on this product? <input type="checkbox"/> No<br/>           If Yes, is it managed with a pharmacy registry? <input type="text"/><br/>           Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No<br/>           Limited Distribution Requirement <input type="text"/><br/>           Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p><b>REMS:</b></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/><br/>           Supplier Manages REMS registry exclusively: <input type="text"/><br/>           Wholesale distributor support: <input type="text"/><br/>           Provider Name: <input type="text"/> DEA #: <input type="text"/><br/>           Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/><br/>           NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p><b>Registry:</b></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/><br/>           Comments <input type="text"/></p>  |  |   |  |
| <p style="text-align: center;"><b>ADD'L STORAGE INFORMATION</b></p> <p>Is the Product...<br/>           Controlled Substance? <input type="checkbox"/> Yes <input type="checkbox"/> No    Controlled Substance Code <input type="text"/> CIII<br/>           Controlled by State(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No    Listed Chemical (List I or II) <input type="checkbox"/> No<br/>           ARCOS Reportable? <input type="checkbox"/> No    If yes, indicate which: <input type="text"/><br/>           Schedule No. <input type="text"/> 3    Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>  |  |   |  |
| <p style="text-align: center;"><b>CLASS OF TRADE RESTRICTION:</b></p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>  |  |   |  |
| <p style="text-align: center;"><b>RETURN INSTRUCTIONS</b></p> <p>Contact tel. # if product received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>  |  |   |  |
| <p style="text-align: center;"><b>MISCELLANEOUS NOTES and/or Image of Product Barcode:</b></p> <p><input type="text"/></p>  |  |   |  |



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

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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="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></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"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p> | <p><b>Purchase order daily receipt cut off time by supplier</b></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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>   |
| Expedited Freight Charges or Other Designated Drop Ship Fees:   | Overnight and Priority Overnight PO Processing   |
| <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><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction:   |  |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>  |  |
| Other Data Information Required to Process PO:  | Return Instructions  |
| <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>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>   |
| Miscellaneous Notes:  | ADDITIONAL INFORMATION   |
| <p><input type="text"/></p>   | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |