



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

Version 2020

Introduction Type:  Post Launch Change

Final Version

Date:

| PRODUCT INFORMATION   |  |
|---|--|
| Company Name:   | <input type="text" value="Xiromed LLC"/>                             |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | <input type="text" value="212995"/>                                  |
| DUNS:   | <input type="text" value="080228637"/>                               |
| Proprietary Name (if Applicable) and Established Name:              | <input type="text" value="Deferasirox Tablets, 90mg"/>               |
| Selling Unit NDC:   | <input type="text" value="70700-269-30"/>                            |
| UDI   | <input type="text" value=""/>  |
| Description:  | <input type="text" value="Deferasirox Tablets, 90mg - 30ct Bottle"/> |
| Active Ingredient(s):   | <input type="text" value="Deferasirox"/>                             |
| URL for Additional Product Information:                             | <input type="text" value=""/>  |
| Address:  | <input type="text" value="180 Park Ave"/>                            |
| City:   | <input type="text" value="Florham Park"/>                            |
| Key Contact:  | <input type="text" value="Xiromed Regulatory"/>                      |
| Phone Number:   | <input type="text" value="844-947-6633"/>                            |
| Product Therapeutic Classification:                                 | <input type="text" value="Iron Chelating Agent"/>                    |
| Application:  | <input type="text" value="ANDA"/>                                    |
| State:  | <input type="text" value="NJ"/>                                      |
| Address 2:  | <input type="text" value="Suite 101"/>                               |
| Zip:  | <input type="text" value="07932"/>                                   |
| Email:  | <input type="text" value="usregulatory@xiromed.com"/>                |
| Fax:  | <input type="text" value="862-286-0932"/>                            |
| UPC:  | <input type="text" value="370700269305"/>                            |
| CVX Code:   | <input type="text" value=""/>  |
| MXV Code:   | <input type="text" value=""/>  |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS*                            |  |
|---|--|
| a. Temperature – Indicate the USP temperature range for this product. | <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> |
| Temperature Range   | <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> |
| Other Temperature Range Requirement (write in)                        | <input type="text" value=""/>  |
| Notes   | <input type="text" value=""/>  |
| Is this product to be shipped to customers on ice?                    | <input type="text" value="No"/>  |
| Is this product to be shipped to customers on dry ice?                | <input type="text" value="No"/>  |
| b. Contact for temperature excursion questions:                       | <input type="text" value="Xiromed Quality"/>                                     |
| Name:   | <input type="text" value="Xiromed Quality"/>                                     |
| Number:   | <input type="text" value="844-947-6633"/>  |
| Group E-mail:   | <input type="text" value="US-Quality-Xiromed@xiromed.com"/>                      |
| c. Special regulations for product in any states?                     | <input type="text" value="No"/>  |
| Special returns requirements for this product?                        | <input type="text" value="No"/>  |
| d. Store product (unit of sale) upright?                              | <input type="text" value="Yes"/>   |
| Protect product (unit of sale) from light?                            | <input type="text" value="Yes"/>   |
| e. Shelf life:  | <input type="text" value="24"/>  |
| Initial shelf life at launch (if different):                          | <input type="text" value=""/>  |

| ADDITIONAL PRODUCT INFORMATION                                      |                                  | PRODUCT DESCRIPTION INFORMATION                               |   |
|---|----------------------------------|---|---|
| The product is a legend device?                                     | <input type="text" value="No"/>  | Is the Product... Direct-Ship Only                            | <input type="text" value="Neither"/>                                |
| If yes, enter class # a product kit?                                | <input type="text" value=""/>    | Is the Product... Orphan Drug Status                          | <input type="text" value=""/>                                       |
| If yes, list NDCs of component parts reverse numbered?              | <input type="text" value=""/>    | FDA Approval Status   | <input type="text" value=""/>                                       |
| co-licensed?  | <input type="text" value="No"/>  | Allergens Present   | <input type="text" value="Not made with natural rubber latex."/>    |
| latex-free?   | <input type="text" value="No"/>  | Country of Origin   | <input type="text" value="India"/>                                  |
| preservative-free?  | <input type="text" value="Yes"/> | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/>                                     |
| correctional institution block?                                     | <input type="text" value="Yes"/> | Product Shape:  | <input type="text" value="Film-coated, oval biconvex"/>             |
| opioid?   | <input type="text" value="No"/>  | Product Color:  | <input type="text" value="Blue"/>                                   |
| Cannabinoid?  | <input type="text" value="No"/>  | Product Imprint:  | <input 90"="" on="" one="" side"="" type="text" value="Debossed "/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text" value=""/>    | Size:   | <input type="text" value="30 Count Bottle"/>                        |
| If Unit Dose, indicate NDC here:                                    | <input type="text" value=""/>    | Strength:   | <input type="text" value="90mg"/>                                   |
|   |                                  | Dosage Form:  | <input type="text" value="Tablets"/>                                |

| ORDER INFORMATION                       |  |
|---|--|
| Unit of Sale                            | <input checked="" type="checkbox"/> Bottle |
| Box/Carton                              | <input type="checkbox"/>                   |
| Ampule                                  | <input type="checkbox"/>                   |
| Glass                                   | <input type="checkbox"/>                   |
| Tube                                    | <input type="checkbox"/>                   |
| Vial Liquid Sgl                         | <input type="checkbox"/>                   |
| Vial Liquid Multi                       | <input type="checkbox"/>                   |
| Vial Powder Sgl                         | <input type="checkbox"/>                   |
| Vial Power Multi                        | <input type="checkbox"/>                   |
| Other: Write In                         | <input type="text" value=""/>              |
| What is the NDC selling unit?           | <input type="text" value="1 Bottle"/>      |
| (Write-in, e.g. 1 Box of 10 Vials)      | <input type="text" value=""/>              |
| Minimum order quantity?                 | <input type="text" value="Yes"/>           |
| If Yes, how many of which package type? | <input type="text" value="12"/>            |
| Each                                    | <input type="text" value=""/>              |
| Inner/ Carton/Pack                      | <input type="text" value=""/>              |
| Case                                    | <input type="text" value=""/>              |

| FOR GENERIC DRUG PRODUCTS                   |   |
|---|---|
| I. Orange Book Rating:                      | <input type="text" value="AB"/>                                 |
| II. Generic Equivalent to What Brand?:      | <input type="text" value="Jadenu"/>                             |
| <input type="checkbox"/> Authorized Generic | *If Authorized Generic, other section fields are not applicable |

| PHARMACY ORDER / BILL UNIT   |  |
|------------------------------|--|
| Rec. sell unit to customer?  | <input type="text" value="1 Bottle"/>    |
| Rx billing unit to pharmacy: | <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?     | <input type="text" value="Yes"/>           |
| Is product exempt from DSCSA?                            | <input type="text" value="No"/>            |
| If yes, select exemption:                                | <input type="text" value=""/>              |
| Other exemption - Write in:                              | <input type="text" value=""/>              |
| Is product repackaged?                                   | <input type="text" value="No"/>            |
| Is product sold by manufacturer's exclusive distributor? | <input type="text" value="No"/>            |
| Has FDA granted waiver/exception/exemption for product?  | <input type="text" value="No"/>            |
| GLN:   | <input type="text" value="0370700000007"/> |
| If Yes, was original product purchased direct from mfr?  | <input type="text" value=""/>              |
| If yes, attach documentation from FDA.                   | <input type="text" value=""/>              |

| ITEM AND PACKING INFORMATION  |             |                        |       |        |               |           |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-----------|
| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | # Pieces: |
|                               |             | Depth                  | Width | Height |               |           |
| Box/Carton/Bundle/Inner Pack: |             |                        |       |        | 0             |           |
| Case:                         | 1.44        | 7.625                  | 5.75  | 3.375  | 147.97266     | 12        |
| Pallet:                       |             |                        |       |        | 0             |           |

| GTIN AND HIBCC PRODUCT INFORMATION       |          |       |                |                     |
|--|----------|-------|----------------|---------------------|
| Saleable Unit of Measure                 | Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
| Item/Each                                | 1        |       | 00370700269305 |                     |
| Box/Carton/Bundle/Inner Pack             |          |       |                |                     |
| <input checked="" type="checkbox"/> Case | 12       |       | 10370700269302 |                     |
| Pallet                                   |          |       |                |                     |

| COST INFORMATION        |                                      | WHOLESALE USE ONLY: |                               |
|-------------------------|--------------------------------------|---------------------|-------------------------------|
| Regular Cost            | <input type="text" value=""/>        | Vendor #:           | <input type="text" value=""/> |
| Invoice Cost (WAC) (\$) | <input type="text" value="\$15.00"/> | Whsl. Code #:       | <input type="text" value=""/> |
| As of date:             | <input type="text" value=""/>        | Fineline Code:      | <input type="text" value=""/> |

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

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?  No
    - 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?  No
- Is this product regulated for shipment by DOT?  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
- e. Inhalation Hazard?

- 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
  - e. Inhalation Hazard?

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#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No      Controlled Substance Code
- Controlled by State(s)?  No      Listed Chemical (List I or II)  No
- 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:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug?  No  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### 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

### 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:

