



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

Version 2021

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Strides Pharma Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	76744
Medical Device Class, if applicable:	
DUNS:	11-8344-504
Proprietary Name (If Applicable) and Established Name:	Testosterone Gel 1%
Selling Unit NDC:	64380-0152-02
Unit of Use NDC:	
UPC:	364380152026
UDI	
CVX Code:	
MVX Code:	
Description:	Testosterone Gel 1% is supplied in unit-dose aluminum foil packets in cartons of 30. Each packet of 5 g gel contains 50 mg testosterone.
Active Ingredient(s):	Testosterone
URL for Additional Product Information:	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=20c26428-81fe-4edb-99ee-637006b10635
Address:	1 Ram Ridge Rd Chestnut Ridge
Address 2:	
State:	NY
Zip:	10977
Key Contact:	
Phone Number:	609-773-5008
Email:	stridescustomerservice@stridesusa.com
Fax:	609-935-0806
Product Therapeutic Classification:	androgen

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	Store at 25°C Excursions 15° to 30°C
Notes	
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:	
Name:	Petronia Anderson
Number:	845.682.3200
Group E-mail:	petronia.anderson@stridesusa.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	
a legend device?	<input type="text" value="No"/>	Is the Product... Neither	
if yes, enter class #		Orphan Drug Status	
a product kit?	<input type="text" value="No"/>	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	
reverse numbered?	<input type="text" value="No"/>	Country of Origin	USA
co-licensed?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
latex-free?	<input type="text" value="Yes"/>	Size:	30
preservative-free?	<input type="text" value="Yes"/>	Strength:	1% 50 mg
correctional institution block?	<input type="text" value="No"/>	Dosage Form:	Sachet
opioid?	<input type="text" value="No"/>	Product Shape:	NA
Cannabinoid?	<input type="text" value="No"/>	Product Color:	Clear
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>	Product Imprint:	NA
If Unit Dose, indicate NDC here:			

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	Carton of 30 sachet
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity?
<input type="checkbox"/> Glass	<input type="text" value="Yes"/>
<input type="checkbox"/> Tube	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Sgl	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value=""/> Inner/Cartron/Pack
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value=""/> Case
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB1
II. Generic Equivalent to What Brand?:	Androgel / N021015
<input checked="" 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:
<input type="text" value="1 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?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	
Other exemption - Write in:	
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"/>
If yes, attach documentation from FDA.	
GLN:	0359556421464
GCP:	
If yes, was original product purchased direct from mfr?	<input type="text" value=""/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.4	3.5	2.25	4.5	35.4375	1
Box/Cartron/Bundle/Inner Pack:	N/A	N/A	N/A	N/A	N/A	N/A
Case:	10	19.375	5.313	11.438	1177.4206	24
Pallet:	700	48	48	40	92160	1536

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		00364380152026	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		50364380152021	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$190.00	Whsl. Code #:	
As of date:	8/1/2022	Fineline Code:	

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:

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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?
 - Is the product a CA Prop 65 carcinogen? Yes
 - 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?
(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?
(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? Yes No Controlled Substance Code
- Controlled by State(s)? Yes No Listed Chemical (List I or II) No
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. 3 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
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:
NFPA Storage Level:

Is the product a NIOSH hazardous drug? Yes No
If yes, indicate which: Group 3 items (primarily adverse reproductive effects)

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes
If Yes, is it managed with a pharmacy registry? Yes No
Website URL:

Med Guide Required Yes No
Limited Distribution Requirement Yes No
Comments / Details: (For example, iPledge program?)

REMS: No Yes
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: Yes No
Wholesale distributor support: Yes No
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: Yes No
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:
Is product returnable for credit: Yes No
URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? Yes No
If so, which states? Other requirements? Comments?



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

Version 2021

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