



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212517
DUNS:	079391286
Proprietary Name (If Applicable) and Established Name:	Naproxen Tablets USP, 375 mg, 100's (BS=1,066,666)
Selling Unit NDC:	50228-435-01
Individual Unit NDC:	1 Bottle
UPC:	350228435017
UDI	
CVX Code:	
MVX Code:	
Description:	Light Yellow Capsule shaped tablets debossed with "SG" on one side and "435" on the other side
Active Ingredient(s):	Naproxen
URL for Additional Product Information:	
Address:	89 Arkay Drive
City:	Hauppauge
Key Contact:	Siva Reddy, P.V.
Phone Number:	631-424-2727 XT 107, 631-524-5509
Product Therapeutic Classification:	Non steroidal anti inflammatory
Application:	ANDA

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Temperature Range	
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Siva Reddy, P.V.
Number:	631-424-2727 XT 107, 631-524-5509
Group E-mail:	sivareddy@sciegenpharm.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Unit of Use	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	USA
Is this product covered under the Trade Agreements Act (TAA)?	Yes

PRODUCT DESCRIPTION INFORMATION	
Size:	0.2559 x 0.5512
Strength:	375 mg
Dosage Form:	Tablet
Product Shape:	Capsule
Product Color:	Light Yellow
Product Imprint:	SG on one side and 435 on other side

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Yes Bottle	50228-435-01
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	Each
	Inner/ Carton/Pack
	3 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Naprosyn (Naproxen) Tablets
<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:
<input type="checkbox"/> Bottle	<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
GLN:	035022800000
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.13	NA	3	1.73	#VALUE!	Tablets per B
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	4.5	12.2	4.5	8.4	461.16	Bottles per C
Pallet:	720	48	48	40	92160	Cases per p
UPC:	Case:	350228435017				
	Carton:					

GTIN PRODUCT INFORMATION							
Serialized?	Level	Saleable Unit	Quantity	GTIN-14			
Yes	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	2D	<input checked="" type="checkbox"/>	1	00350228435017
If not, when?		Box/Carton/Bundle/Inner Pack		2D			
Items aggregated?	No	Case	<input checked="" type="checkbox"/>	2D	<input checked="" type="checkbox"/>	24	20350228435011
		Pallet		2D			
				2D			
				2D			
				2D			
				2D			
				2D			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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:

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?
(If yes, attach SDS with special instructions.)
e. Does the product contain DEHP? No
Is this product regulated for shipment by DOT or 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? No

Is the product restricted for air shipment? If so, indicate restriction:
Passenger
Cargo
Passenger & Cargo

Is this a reportable quantity?
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 by State(s)? No
ARCOS Reportable?
Schedule No. (inc. N for non-narcotic)
Controlled Substance Code
Listed Chemical (List I or II)
If yes, indicate which:
Is it a scheduled listed chemical product?:

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:

SDS Hazard Classification
[X] 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:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
If Yes, is it managed with a pharmacy registry?
Website URL:
Comments / Details: (For example, iPledge program?)

REMS:
REMS Program Manager Name:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name:
Site Enrollment Number assigned by Supplier:
Phone:
DEA #:
PCPDP #:
NPI #:

Registry:
Registry Program Contact Name:
Phone:
Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 631-524-5509
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states? No
If so, which states? Other requirements? Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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"/> _____ Fax Number: _____ c. Fax <input type="checkbox"/> _____ Fax Number: _____ d. Phone only <input type="checkbox"/> _____ Phone No.: _____ e. Supplier Web Site only <input type="checkbox"/> _____ 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: _____ PO Receipt cut off time: _____ 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: _____ PO Receipt Cut off time: _____ Saturday Overnight receipt available: _____ PO Receipt Cut off time: _____ Order receipt method: Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: _____ Other fees apply: _____
Class of Trade Restriction:	Return Instructions
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="checkbox"/> _____ Comments: _____	Contact # if product is 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? _____
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____	Is product order for scheduled patient procedure? _____ Is product order for restocking purposes? _____
Miscellaneous Notes:	
