



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date: 7/25/2017

PRODUCT INFORMATION

Company Name: TWI Pharmaceuticals USA, Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 201408
 DUNS: 080216652
 Proprietary Name (If Applicable) and Established Name:
 Selling Unit NDC: 24979-533-01 Individual Unit NDC: 24979-533-01 UPC: 3 24979 533 01 8
 UDI: CVX Code: MVX Code:
 Description: Guanfacine Extended Release Tablets - 1mg/100 Count
 Active Ingredient(s): Guanfacine Hydrochloride
 URL for Additional Product Information: www.twipharma.com
 Address: 115 West Century Road -Suite 180 Address 2:
 City: Paramus State: NJ Zip: 07652
 Key Contact: Linda Nesbitt Email: linda.nesbitt@twipharma.com
 Phone Number: Fax:
 Product Therapeutic Classification:

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):
 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: Linda Nesbitt
 Number: 201-762-1405
 Group E-mail: linda.nesbitt@twipharmausa.com
 c. Special regulations for product in any states? No
 Special returns requirements for this product? No
 d. Store product (unit of sale) upright? No
 Protect product (unit of sale) from light? No
 e. Shelf life: Initial shelf life at launch (if different): 24 Months

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: Taiwan
 Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 100 Count
 Strength: 1mg
 Dosage Form: Tablet
 Product Shape: Round, Bi-Convex
 Product Color: White
 Product Imprint: 1mg on one side and A533 on the other side

ORDER INFORMATION

Unit of Sale: Bottle, Box/Carton, Ampule, Glass, Tube, Vial Liquid Sgl, Vial Liquid Multi, Vial Powder Sgl, Vial Power Multi, Other: Write In
 What is the NDC selling unit? 1 bottle containing 100 Tablets (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? Yes
 If Yes, how many of which package type?
 Each, Inner/Carton/Pack, Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Intuniv

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 Bottle (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy: Each, Gram, 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: *0324979000008
 If Yes, was original product purchased direct from mfr?
 If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	54 g	2 in.	4 in.	2 in.	16 in.	1
Box/Carton/Bundle/Inner Pack:	1.6 lbs.	7.5 in.	4 in.	5.5 in.	165 in.	12
Case:	3.5 lbs.	8 in.	4.5 in.	12 in.	432 in.	24
Pallet:	435 lbs.	46 in.	38 in.	40 in.	69,920 in.	162
UPC:	Case: 3 24979 533 01 8					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Level	Item	Saleable Unit	Quantity	GTIN-14
No				1	00324979533018
Q4 2017		Box/Carton/Bundle/Inner Pack		12	30324979533019
Yes		Case	X	24	60324979533010
		Pallet			

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$) \$41.96
 Federal Excise Tax Per Unit of Sale
 As of date:
 WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fineline Code:

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? 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 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? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 (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? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No

If yes, indicate which:

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 No

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/>	
Is the product a NIOSH hazardous drug? No	
If yes, indicate which: <input style="width: 100%;" type="text"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input style="width: 100%;" type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? No	
If Yes, is it managed with a pharmacy registry? <input style="width: 100%;" type="text"/>	
Website URL: <input style="width: 100%;" type="text"/>	
Comments / Details: (For example, iPledge program?) <input style="width: 100%; height: 20px;" type="text"/>	
REMS: <input style="width: 100%;" type="text"/>	
REMS Program Manager Name: <input style="width: 100%;" type="text"/>	Phone: <input style="width: 100%;" type="text"/>
Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/>	
Wholesale distributor support: <input style="width: 100%;" type="text"/>	
Provider Name: <input style="width: 100%;" type="text"/>	DEA #: <input style="width: 100%;" type="text"/>
Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/>	PCPDP #: <input style="width: 100%;" type="text"/>
	NPI #: <input style="width: 100%;" type="text"/>

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? 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																																		
<p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 15%;"><input type="text"/></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 20%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>					b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>			c. Fax	<input type="text"/>	Fax Number:	<input type="text"/>			d. Phone only	<input type="text"/>	Phone No.:	<input type="text"/>			e. Supplier Web Site only	<input type="text"/>	Site Address:	<input type="text"/>			Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 80%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 15%;" type="text"/> Hours <input style="width: 15%;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
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Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input style="width: 80%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 80%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 80%;" type="text"/></p> <p>Comments: <input style="width: 95%; height: 60px;" type="text"/></p>	<p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input style="width: 80%;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 80%;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 80%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Phone:</td> <td style="width: 15%;"><input style="width: 50%;" type="text"/></td> <td style="width: 15%;">Phone #:</td> <td style="width: 15%;"><input style="width: 50%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 50%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 50%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 50%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input style="width: 50%;" type="text"/>	Phone #:	<input style="width: 50%;" type="text"/>	Fax:	<input style="width: 50%;" type="text"/>	Fax #:	<input style="width: 50%;" type="text"/>	EDI:	<input style="width: 50%;" type="text"/>														
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Class of Trade Restriction:	Return Instructions																																		
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input style="width: 95%; height: 60px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 80%;" type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input style="width: 80%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 95%; height: 40px;" type="text"/></p>																																		
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																		
<p>Patient Procedure Date: <input style="width: 80%;" type="text"/></p> <p>Physician Name: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 80%;" type="text"/></p> <p>Physician State License #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 80%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>																																		
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