



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	210188
DUNS:	081468959
Proprietary Name (If Applicable) and Established Name:	Ranolazine Extended-Release Tablets 500mg
Selling Unit NDC:	72578-064-14
Individual Unit NDC:	
UPC:	372578064143
UDI	N/A
CVX Code:	
MXV Code:	N/A
Description:	light orange colored, oval shaped, beveled edge, biconvex, film coated tablets debossed with "588" on one side and plain on other side
Active Ingredient(s):	Ranolazine
URL for Additional Product Information:	www.vionausa.com
Address:	20 Commerce Drive
City:	Cranford
Key Contact:	Chris Urbanski
Phone Number:	908-956-0600 x109
Product Therapeutic Classification:	Antianginal

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	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"/>
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: <input type="text" value="Customer Service"/> Number: <input type="text" value="888-304-5022"/> Group E-mail: <input type="text" value="Vionacs@eversana.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?	<input type="text" value="Yes"/>
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	
Is the Product... a legend device?	<input type="text" value="No"/>
reverse numbered?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>
Is the Product... Direct-Ship Only	<input type="text"/>
Is the Product... Neither	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value="No"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text" value="India"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	<input type="text" value="60ct"/>
Strength:	<input type="text" value="500mg"/>
Dosage Form:	<input type="text" value="Extended-Release Tablets"/>
Product Shape:	<input type="text" value="Oval"/>
Product Color:	<input type="text" value="Light Orange"/>
Product Imprint:	<input type="text" value="588"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 60 Extended-Release Tablets"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/Carton/Pack
<input type="checkbox"/> Vial Power Multi	<input type="text" value="1"/> Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic
II. Generic Equivalent to What Brand?:	<input type="text" value="Ranexa"/> *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 Each"/>	<input type="text"/>
(Write-in, e.g. 1 Vial)	<input type="text" value="Each"/>
	<input type="text" value="Gram"/>
	<input type="text" value="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:	<input type="text"/>
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="0372578000004"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.15	1.675	3.191	1.675	8.95274938	1
Box/Carton/Bundle/Inner Pack:	N/A	N/A	N/A	N/A	#VALUE!	N/A
Case:	4.87	10.24	4.53	6.89	319.607808	24
Pallet:	628.19	47.24	49.21	39.37	91522.6673	3,024
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	
		Item	Unit			
If not, when?	<input type="text"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	00372578064143	
Items aggregated?	<input type="text"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	24	40372578064141	
		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3,024	50372578064148	
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text"/>	Whsl. Code #:	<input type="text"/>
Federal Excise Tax Per Unit of Sale	<input type="text"/>	Fineline Code:	<input type="text"/>
As of date:	<input type="text"/>		

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?

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 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?:

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

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: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:
Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes

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: 60%;" 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: 60%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 60%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 60%;" 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: 60%;" 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: 60%;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" 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: 60%;" type="text"/></td> <td style="width: 15%;">Phone #:</td> <td style="width: 15%;"><input style="width: 60%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 60%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 60%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 60%;" 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: 60%;" type="text"/>	Phone #:	<input style="width: 60%;" type="text"/>	Fax:	<input style="width: 60%;" type="text"/>	Fax #:	<input style="width: 60%;" type="text"/>	EDI:	<input style="width: 60%;" 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: 60%;" type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input style="width: 60%;" 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: 60%;" 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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