



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Pre-Launch Change Post Launch Change Final VersionDate:

PRODUCT INFORMATION					
Company Name:	<input type="text" value="Viona Pharmaceuticals Inc."/>		Application:	<input type="text" value="ANDA"/>	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="090961"/>				
DUNS:	<input type="text" value="081468959"/>				
Proprietary Name (If Applicable) and Established Name:	<input type="text" value="Memantine Hydrochloride Tablets, USP 10 mg"/>				
Selling Unit NDC:	<input type="text" value="72578-004-14"/>	Individual Unit NDC:	<input type="text" value="72578-004-14"/>	UPC:	<input type="text" value="372578004149"/>
UDI	<input type="text" value="N/A"/>	CVX Code:	<input type="text"/>	MVX Code:	<input type="text" value="N/A"/>
Description:	<input type="text" value="white to off white, capsule shaped, biconvex film coated tablets debossed with 'ZF 40' on one side and other side is plain"/>				
Active Ingredient(s):	<input type="text" value="Memantine Hydrochloride, USP"/>				
URL for Additional Product Information:	<input type="text" value="www.vionausa.com"/>				
Address:	<input type="text" value="20 Commerce Drive"/>	Address 2:	<input type="text" value="Suite 340"/>		
City:	<input type="text" value="Cranford"/>	State:	<input type="text" value="NJ"/>	Zip:	<input type="text" value="07016"/>
Key Contact:	<input type="text" value="Chris Urbanski"/>		Email:	<input type="text" value="Curbanski@vionausa.com"/>	
Phone Number:	<input type="text" value="908-956-0600 x109"/>		Fax:	<input type="text" value="908-514-4005"/>	
Product Therapeutic Classification:	<input type="text" value="Orally Active NDMA Receptor Antagonist"/>				

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°)"/>
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?	
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
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="Italy"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	<input type="text" value="60 count"/>
Strength:	<input type="text" value="10 mg"/>
Dosage Form:	<input type="text" value="Tablets"/>
Product Shape:	<input type="text" value="Capsule Shape"/>
Product Color:	<input type="text" value="White to Off-White"/>
Product Imprint:	<input type="text" value="'ZF 40'"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 60 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"/>
<input type="checkbox"/> Vial Powder Multi	<input type="text" value="1"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text" value="1"/> Case

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="Namenda"/> *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="Each"/>	<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"/> GLN: <input type="text" value="0372578000004"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text"/>
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"/>

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.08	1.55	2.39	1.55	5.741975	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	3.63	7.28	3.43	10.83	270.429432	24
Pallet:	669.17	47.24	49.21	39.37	91522.6673	4,320
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Yes	Level	Saleable Unit		Quantity	GTIN-14
			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
If not, when?	<input type="text"/>	Item	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	00372578004149
Items aggregated?	<input type="text" value="Yes"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
		Case	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	24	40372578004147
		Pallet	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4,320	50372578004144
			<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"/>		

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 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: 10%;"><input type="checkbox"/></td> <td style="width: 20%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="checkbox"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="checkbox"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>d. Phone only</td> <td><input type="checkbox"/></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="checkbox"/></td> <td>Site Address:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input 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 type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table>	a. EDI	<input type="checkbox"/>					b. Autofax	<input type="checkbox"/>	Fax Number:	<input type="text"/>			c. Fax	<input type="checkbox"/>	Fax Number:	<input type="text"/>			d. Phone only	<input type="checkbox"/>	Phone No.:	<input type="text"/>			e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input type="text"/>			Name:	<input type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
a. EDI	<input type="checkbox"/>																																		
b. Autofax	<input type="checkbox"/>	Fax Number:	<input type="text"/>																																
c. Fax	<input type="checkbox"/>	Fax Number:	<input type="text"/>																																
d. Phone only	<input type="checkbox"/>	Phone No.:	<input type="text"/>																																
e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input type="text"/>																																
Name:	<input type="text"/>																																		
Phone:	<input type="text"/>																																		
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input 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="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 10%;"><input type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input type="text"/></td> <td>Fax #:</td> <td><input type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input type="text"/>	Phone #:	<input type="text"/>	Fax:	<input type="text"/>	Fax #:	<input type="text"/>	EDI:	<input type="text"/>														
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Fax:	<input type="text"/>	Fax #:	<input type="text"/>																																
EDI:	<input type="text"/>																																		
Class of Trade Restriction:	Return Instructions																																		
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments?</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div>																																		
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																		
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>																																		
Miscellaneous Notes:																																			
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