



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION			
Company Name: CREEKWOOD PHARMACEUTICALS LLC		Application: ANDA	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A202047			
Medical Device Class, if applicable:			
DUNS: 118582565			
Proprietary Name (If Applicable) and Established Name: Rizatriptan Benzoate Tablets, USP 5 mg			
Selling Unit NDC: 82619-111-05	Unit of Use NDC: 82619-111-05	UPC: 382619111057	
UDI: NA	CVX Code:	MXV Code: NA	
Description: Rizatriptan Benzoate, USP 5 mg tablets are Pale pink colored, capsule shaped uncoated tablets debossed with '388' on one side and plain on other side.			
Active Ingredient(s): Rizatriptan Benzoate USP			
URL for Additional Product Information:			
Address: 1130 US 46 W	Address 2: Suite 21		
City: Parsippany	State: NJ	Zip: 07054	
Key Contact: Paul Thomas	Email: paul@creekwoodpharma.com		
Phone Number: 1-732-344-022	Fax:		
Product Therapeutic Classification: ANTIMIGRAINE			

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"/>
Notes	<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="SUJIT SAKPAL"/>
Number:	<input type="text" value="551-303-9330"/>
Group E-mail:	<input type="text" value="sujit@creekwoodpharma.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 a legend device? <input type="text" value="No"/>	Is the Product... Direct-Ship Only <input type="text"/>
if yes, enter class # <input type="text"/>	Is the Product... Unit of Use <input type="text"/>
a product kit? <input type="text" value="No"/>	Orphan Drug Status <input type="text"/>
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	FDA Approval Status <input type="text"/>
co-licensed? <input type="text" value="No"/>	Allergens Present <input type="text"/>
latex-free? <input type="text" value="Yes"/>	Presence of Lactose, dairy Product <input type="text"/>
preservative-free? <input type="text" value="Yes"/>	Country of Origin <input type="text" value="INDIA"/>
correctional institution block? <input type="text" value="No"/>	Product Shape: CAPSULE SHAPED
opioid? <input type="text" value="No"/>	Product Color: Pale Pink
Cannabinoid? <input type="text" value="No"/>	Product Imprint: 388
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text" value="No"/>	
If Unit Dose, indicate NDC here: <input type="text"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 box of 18 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	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text" value="90"/> 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 <small>*If Authorized Generic, other section fields are not applicable</small>
II. Generic Equivalent to What Brand?: <input type="text" value="MAXALT"/>	

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? <input type="text" value="1 box of 12 Tablets"/>	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Each
	<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="850045940003"/>		
Is product exempt from DSCSA? <input type="text"/>	GCP: <input type="text" value="850045940"/>		
If yes, select exemption: <input type="text"/>	If yes, was original product purchased direct from mfr? <input type="text"/>		
Other exemption - Write in: <input type="text"/>	Provide source manufacturer for repackaged product <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"/>			
If yes, attach documentation from FDA. <input type="text"/>			

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.04	4.02	0.79	1.89	5.98	1
Case:	11.2	11.89	10.32	13.50	1656.19	90
Pallet:	454	42	35	40	58800	6480

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00382619111057"/>	<input type="text" value="382619111057"/>
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text" value="90"/>	<input type="text"/>	<input type="text" value="20382619111051"/>	
<input checked="" type="checkbox"/> Case	<input type="text" value="6480"/>	<input type="text"/>		
<input checked="" type="checkbox"/> Pallet		<input type="text"/>		

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"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">Hazardous Waste Identification</p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <input type="checkbox"/> No If Yes, is it managed with a pharmacy registry? <input type="text"/> Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No Limited Distribution Requirement <input type="checkbox"/> No Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: <input type="checkbox"/> No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/> NPI #: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p> <p>Registry: <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p> </div>	<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"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</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 type="text"/></p>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf</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 type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							



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

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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"/> Yes 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" value="210"/> Units Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text" value="Direct customer solutions (R & S)"/> Phone: <input type="text" value="1-800-655-7556"/>	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: 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 and Priority Overnight PO Processing 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: 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="checkbox"/> Comments: <input type="text"/>	Return Instructions 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"/> ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>
Other Data Information Required to Process PO: 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"/> Miscellaneous Notes: <input type="text"/>	