



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

Version 2024 Introduction Type: Final Version Date:

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	211219
Medical Device Class, if applicable:	
DUNS:	118694141
Proprietary Name (If Applicable) and Established Name:	Eslicarbazepine Acetate Tablets
Selling Unit NDC:	59746-0720-30
Unit of Use NDC:	
CVX Code:	
UPC:	3-59746-720-30-8
MXV Code:	
Description:	Eslicarbazepine Acetate 800mg Tablets
Active Ingredient(s):	Eslicarbazepine Acetate 800mg
URL for Additional Product Information:	www.cadista.com/products/full-product-list
Address:	790 Township Line Road
City:	Yardley
Key Contact:	Customer Service
Phone Number:	(800) 313-4623
Product Therapeutic Classification:	Anticonvulsant

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="Customer Service"/>
	Number: <input type="text" value="(800) 313-4623"/>
	Group E-mail: <input type="text" value="customer.service@cadista.com"/>
c. Special regulations for product in any states?	<input type="text" value="No"/>
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="No"/>
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>
a legend device?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text"/>
if yes, enter class #		FDA Approval Status	<input type="text"/>
a product kit?	<input type="text" value="No"/>	Allergens Present	<input type="text"/>
if yes, list NDCs of component parts		Country of Origin	<input type="text" value="India"/>
reverse numbered?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>		
latex-free?	<input type="text" value="Yes"/>		
preservative-free?	<input type="text" value="No"/>		
correctional institution block?	<input type="text" value="Yes"/>		
opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
		Size:	<input type="text" value="30 count"/>
		Strength:	<input type="text" value="800mg"/>
		Dosage Form:	<input type="text" value="Tablet"/>
		Product Shape:	<input type="text" value="Oblong"/>
		Product Color:	<input type="text" value="White to off white"/>
		Product Imprint:	<input type="text" value="debossed with 'CS4' on one side, functional scoring on other side"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 30 tablets"/>
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<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="48"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	<input type="text" value="Aptiom®"/>

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 Bottle of 30 tablets"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> 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:	<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"/>
If yes, attach documentation from FDA.	<input type="text"/>
GLN:	<input type="text" value="0359746000004"/>
GCP:	<input type="text" value="0359746"/>
If yes, was original product purchased direct from mfr?	<input type="text"/>
Provide source manufacturer for repackaged product	<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:						
Case:	0.12	1.60	1.60	3.46	8.86	1
Pallet:	6.70	12.99	9.84	4.53	579.03	48
					0	

GTIN AND HIBCC PRODUCT INFORMATION					
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00359746720308	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	N	48		40359746720306	
<input type="checkbox"/> Case					
<input type="checkbox"/> Pallet					
		0			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$49.50"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text" value="6/15/2028"/>	Fineline Code:	<input type="text"/>

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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?
 (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT?
 (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 this product regulated for shipment by IATA?
 (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 No

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 Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required No Yes

Limited Distribution Requirement No Yes

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

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?

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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: <table border="0" style="width: 100%; margin-top: 5px;"> <tr> <td style="width: 20px;">a. EDI</td> <td><input type="checkbox"/></td> <td style="width: 20px;">Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>b. Autofax</td> <td><input type="checkbox"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="checkbox"/></td> <td>Phone No.:</td> <td><input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="checkbox"/></td> <td>Site Address:</td> <td><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="checkbox"/></td> <td></td> <td></td> </tr> </table> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <table border="0" style="width: 100%;"> <tr> <td style="width: 20px;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table>	a. EDI	<input type="checkbox"/>	Fax Number:	<input type="text"/>	b. Autofax	<input type="checkbox"/>	Fax Number:	<input type="text"/>	c. Fax	<input type="checkbox"/>	Phone No.:	<input type="text"/>	d. Phone only	<input type="checkbox"/>	Site Address:	<input type="text"/>	e. Supplier Web Site only	<input type="checkbox"/>			Name:	<input type="text"/>	Phone:	<input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> <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"/>
a. EDI	<input type="checkbox"/>	Fax Number:	<input type="text"/>																						
b. Autofax	<input type="checkbox"/>	Fax Number:	<input type="text"/>																						
c. Fax	<input type="checkbox"/>	Phone No.:	<input type="text"/>																						
d. Phone only	<input type="checkbox"/>	Site Address:	<input type="text"/>																						
e. Supplier Web Site only	<input type="checkbox"/>																								
Name:	<input type="text"/>																								
Phone:	<input type="text"/>																								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																								
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 style="width: 100%; height: 50px;" type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> <input type="text"/> Days of week overnight is available: <table border="0" style="margin-left: 20px;"> <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> 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: <table border="0" style="width: 100%;"> <tr> <td style="width: 20px;">Phone:</td> <td><input type="text"/></td> <td style="width: 20px;">Phone #:</td> <td><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> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>	<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"/>				
<input type="checkbox"/>	Monday																								
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Fax:	<input type="text"/>	Fax #:	<input type="text"/>																						
EDI:	<input type="text"/>																								
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 style="width: 100%; height: 50px;" type="text"/>																									
Other Data Information Required to Process PO:	Return Instructions																								
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"/>	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 style="width: 100%; height: 50px;" type="text"/>																								
Miscellaneous Notes:																									
<input style="width: 100%; height: 100px;" type="text"/>	ADDITIONAL INFORMATION																								
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>																								