



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	Citron Pharma LLC	Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	ANDA079170		
Rx Product/Proprietary Name:	Rosuvastatin Calcium Tabs 5 mg 30		
NDC:	57237-168-30	UPC:	357237168301
CVX Code:		MVX Code:	
Description:	Rosuvastatin is in a group of drugs called HMG CoA reductase inhibitors, or "statins." Rosuvastatin reduces levels of "bad" cholesterol (low-density lipoprotein, or LDL) and triglycerides in the blood, while increasing levels of "good" cholesterol (high-		
Active ingredients:	Rosuvastatin Calcium Tabs		
URL for Additional Product Information:			
Address:	2 Tower Center Boulevard Suite 1101	Address 2:	
City:	East Brunswick	State:	NJ
Key Contact:	Kaitlin Alexander	Email:	kalexander@citronpharma.com
Phone Number:	732-227-1515	Fax:	732-227-1513

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input checked="" type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	Vikram Ganesh
Number:	732-917-6062
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
<input type="text"/> 24	Months
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Crestor
III. Generic Equivalent for Brand:	Rosuvastatin

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
DUNS:	078731527
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item		Unit of Sale	What is the NDC selling unit?
Legend Device?	No	<input checked="" type="checkbox"/> Bottle	1 Bottle of 30
State Control?	No	<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	No	<input type="checkbox"/> Ampule	
Co-Licensed?	No	<input type="checkbox"/> Glass	
Controlled Substance?	No	<input type="checkbox"/> Tube	Minimum order quantity? Yes
Schedule No.?		<input type="checkbox"/> Vial Liquid Sgl	
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
Controlled Substance Code:		<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Each
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/Cartron/Pack
Is Item... Unit of Use		<input type="checkbox"/> Other: Write In	<input type="text"/> Case
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
Is it reverse numbered?	No		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.055	1	3.526	1.562	5.507612	1
Box/ Carton:	1.429	10.16	3.53	6.89	247.108472	24
Case:	3.44	11.22	8.46	7.68	728.994816	48
Pallet:	377.14	48	47.56	40	91315.2	4800
UPC:	Case:	50357237168306				
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:		Rec. sell unit to customer?		Size/Strength/Form:		Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Whsl. Code #:		(Write-in, e.g. 1 Vial)		30/5mg/Tablets				
Fineline Code:		Rx billing unit to pharmacy:		Product Shape:	OVAL (Biconvex)			
		<input type="checkbox"/> Each		Product Color:	PINK			
		<input type="checkbox"/> Gram		Product Imprint:	I:29			
		<input type="checkbox"/> Milliliter						

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:



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PRODUCT INFORMATION			
Company Name:	Citron Pharma LLC	Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	ANDA079170		
Rx Product/Proprietary Name:	Rosuvastatin Calcium Tabs 5 mg 90		
NDC:	57237-168-90	UPC:	357237168905
CVX Code:		MVX Code:	
Description:	Rosuvastatin is in a group of drugs called HMG CoA reductase inhibitors, or "statins." Rosuvastatin reduces levels of "bad" cholesterol (low-density lipoprotein, or LDL) and triglycerides in the blood, while increasing levels of "good" cholesterol (high-		
Active ingredients:	Rosuvastatin Calcium Tabs		
URL for Additional Product Information:			
Address:	2 Tower Center Boulevard Suite 1101	Address 2:	
City:	East Brunswick	State:	NJ
Key Contact:	Kaitlin Alexander	Email:	kalexander@citronpharma.com
Phone Number:	732-227-1515	Fax:	732-227-1513

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input checked="" type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	Vikram Ganesh
Number:	732-917-6062
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
<input type="text"/> 24	Months
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Crestor
III. Generic Equivalent for Brand:	Rosuvastatin

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
DUNS:	078731527
Is product exempt from DSCSA?	No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	<input checked="" type="checkbox"/> Bottle
Legend Device?	No	What is the NDC selling unit?	1 Bottle of 90
State Control?	No	(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
ARCOS reportable?	No	Minimum order quantity?	Yes
Co-Licensed?	No	If Yes, how many of which package type?	<input type="text"/>
Controlled Substance?	No	<input type="text"/> Each	
Schedule No.?	<input type="text"/>	<input type="text"/> Inner/ Carton/Pack	
(incl. N for non-narcotic)		<input type="text"/> Case	
Controlled Substance Code:	<input type="text"/>	<input type="text"/> 1	
Hazardous Material/Cytotoxic Agent?	No		
Is Item... Unit of Use	<input type="text"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
Is it reverse numbered?	No		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.062	1	3.526	1.562	5.507612	1
Box/ Carton:	1.587	10.16	3.53	6.89	247.108472	24
Case:	3.75	11.22	8.46	7.68	728.994816	48
Pallet:	408.85	48	47.56	40	91315.2	4800
UPC:	Case:	50357237168900				
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text"/>	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	90/5mg/Tablets			
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input type="text"/>	Product Color:	OVAL (Biconvex)			
		<input type="checkbox"/> Each		Product Imprint:	PINK			
		<input type="checkbox"/> Gram			I:29			
		<input type="checkbox"/> Milliliter						
						As of date: <input type="text"/>		

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PRODUCT INFORMATION			
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Application Number for NDA/ANDA/BLA, Med Device:	ANDA079170		
Rx Product/Proprietary Name:	Rosuvastatin Calcium Tabs 5 mg 1000		
NDC:	57237-168-99	UPC:	357237168998
CVX Code:		MVX Code:	
Description:	Rosuvastatin is in a group of drugs called HMG CoA reductase inhibitors, or "statins." Rosuvastatin reduces levels of "bad" cholesterol (low-density lipoprotein, or LDL) and triglycerides in the blood, while increasing levels of "good" cholesterol (high-		
Active ingredients:	Rosuvastatin Calcium Tabs		
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Address:	2 Tower Center Boulevard Suite 1101	Address 2:	
City:	East Brunswick	State:	NJ
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Phone Number:	732-227-1515	Fax:	732-227-1513

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Number:	732-917-6062
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DUNS:	078731527
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Is product sold by manufacturer's exclusive distributor?	No
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ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
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Legend Device?	No	<input checked="" type="checkbox"/> Bottle	1 Bottle of 1000
State Control?	No	<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	No	<input type="checkbox"/> Ampule	
Co-Licensed?	No	<input type="checkbox"/> Glass	
Controlled Substance?	No	<input type="checkbox"/> Tube	Minimum order quantity? Yes
Schedule No.?		<input type="checkbox"/> Vial Liquid Sgl	
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
Controlled Substance Code:		<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Each
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Inner/Cartron/Pack
Is Item... Unit of Use		<input type="checkbox"/> Other: Write In	<input type="text"/> Case
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
Is it reverse numbered?	No		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.154	1	3.08	1.875	5.775	1
Box/ Carton:	1.929	7.95	3.1	6.06	149.3487	12
Case:	8.88	12.8	9.06	8.86	1027.47648	48
Pallet:	601.4	48	41.46	40	79603.2	3072
UPC:	Case:	50357237168993				
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information	
Vendor #:		Rec. sell unit to customer?		Size/Strength/Form:	1000/5mg/Tablets
Whsl. Code #:		(Write-in, e.g. 1 Vial)		Product Shape:	OVAL (Biconvex)
Fineline Code:		Rx billing unit to pharmacy:		Product Color:	PINK
		<input type="checkbox"/> Each		Product Imprint:	I:29
		<input type="checkbox"/> Gram			
		<input type="checkbox"/> Milliliter			

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
As of date: <input type="text"/>		

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