



# 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 40 mg 30		
NDC:	57237-171-30	UPC:	357237171301
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*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<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 checked="" 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 type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
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
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
<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"/>
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Powder Multi	Each
Is Item... Unit of Use		<input type="checkbox"/> Other: Write In	Inner/ Carton/Pack
If Unit Dose, is item bar coded to unit dose for hospital scanning?			Case
Is it reverse numbered?	No		1

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.075	1	3.526	1.562	5.507612	1
Box/ Carton:	1.904	10.16	3.53	6.89	247.108472	24
Case:	4.39	11.22	8.46	7.68	728.994816	48
Pallet:	472.25	48	47.56	40	91315.2	4800
UPC:	50357237171306					
Case:						
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)		30/40mg/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;32			
		<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 40 mg 90		
NDC:	57237-171-90	UPC:	357237171905
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

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<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 checked="" 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 type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
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
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
<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 90
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"/>
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Power Multi	Each
Is Item... Unit of Use		<input type="checkbox"/> Other: Write In	Inner/ Carton/Pack
If Unit Dose, is item bar coded to unit dose for hospital scanning?			Case
Is it reverse numbered?	No		1

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.139	1	3.747	1.625	6.088875	1
Box/ Carton:	3.446	10.79	3.75	7.32	296.1855	24
Case:	7.52	11.61	8.86	8.07	830.117322	48
Pallet:	605.28	48	40.67	40	78086.4	4800
UPC:	Case:	50357237171900				
	Carton:					

PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer?		Size/Strength/Form:	90/40mg/Tablets
(Write-in, e.g. 1 Vial)		Product Shape:	OVAL (Biconvex)
Rx billing unit to pharmacy:		Product Color:	PINK
<input type="checkbox"/> Each		Product Imprint:	I;32
<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"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

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