**PRODUCT INFORMATION**

- **Company Name:** Citron Pharma LLC
- **Application Number for NDA/ANDA/BLA, Med Device:** ANDA079170
- **Rx Product/Proprietary Name:** Rosuvastatin Calcium Tabs 5 mg 30
- **NDC:** 57237-168-30
- **CVX Code:** MVX Code: 357237168301
- **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:**

**SPECIAL HANDLING AND STORAGE REQUIREMENTS**

- a. Temperature – Indicate the USP temperature range for this product.
  - I. Freezer – between -25 and -10 C (-13° – 14° F)
  - II. Cold – between 2 and 8 C (36° – 46° F)
  - III. Cool – between 8 and 15 C (46° – 59° F)
  - IV. Controlled Room – between 20 and 25 C (68° – 77° F)
  - V. Avoid Excessive Heat – above 40 C (>104° F)
  - VI. Other Temperature Range Requirement (write in)
  - VII. No Requirement

**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: 578731527
- Is product exempt from DSCSA? No
- Other exemption - Write in:
- Is product repackaged? No
- If Yes, was original product purchased direct from mfr? No
- Are any waivers granted for product ID/barcode? No
- If yes, attach documentation from FDA

**ADDITIONAL PRODUCT INFORMATION**

- Is the Product... Direct Ship Item? Yes
- Legend Device? No
- State Control? No
- ARCGS reportable? No
- Co-Licensed? No
- Controlled Substance? No
- Schedule No.? No
- Hazardous Material/Cytotoxic Agent? No
- Controlled Substance Code: 
- Is Item... Unit of Use? 
  - If Unit Dose, is item bar coded to unit dose for hospital scoring? No
  - Is it reverse numbered? No

**ORDER INFORMATION**

- What is the NDC selling unit?
  - 1 Bottle of 30

**ITEM AND PACKING INFORMATION**

- Item: 0.055
- Weight Lbs.
- Dimensions (US msmts.):
  - Depth: 3.526
  - Width: 1.562
- Volume (Cube): 5.507612
- # Pieces: 1
- UPC: 00.53757237168308
- Pallet: 377.14
- Case: 3.44
- Box/Carton: 1.429
- Case: 3.44
- Box/Carton: 1.429
- UPC: 0053757237168308

**PHARMACY ORDER / BILL UNIT**

- Rx billing unit to pharmacy:
  - Each
  - Gram
  - Milliliter

**PHARMACY ORDER / BILL UNIT**

- Item:
  - Product Shape: OVAL (Biconvex)
  - Product Color:
  - Product Imprint: 7.68

**COST INFORMATION**

- Regular Cost Per Unit of Sale ($): 247.108472
- Invoice Cost (WAC) ($) 91315.2
- Federal Excise Tax Per Unit of Sale (Write-in):

**WHOLERLASSER USE ONLY:**

- Rx billing unit to pharmacy:
  - Each
  - Gram
  - 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.
### Standard Pharmaceutical Product Information (Rx Product Only)

**Introduction Type:**

<table>
<thead>
<tr>
<th><strong>PRODUCT INFORMATION</strong></th>
<th><strong>ORDER INFORMATION</strong></th>
<th><strong>ITEM AND PACKAGING INFORMATION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company Name:</strong> Citron Pharma LLC</td>
<td><strong>Unit of Sale</strong></td>
<td><strong>Item</strong></td>
</tr>
<tr>
<td><strong>Application Number for NDA/ANDA/BLA, Med Device:</strong> ANDA079170</td>
<td><strong>Bottle</strong></td>
<td><strong>0.062</strong></td>
</tr>
<tr>
<td><strong>Rx Product/Proprietary Name:</strong> Rosuvastatin Calcium Tabs 5 mg 90</td>
<td><strong>Box/Carton</strong></td>
<td><strong>1.562</strong></td>
</tr>
<tr>
<td><strong>NDC:</strong> 57237-168-90</td>
<td><strong>Unit:</strong></td>
<td><strong>1.562</strong></td>
</tr>
<tr>
<td><strong>UPC:</strong> 357237168905</td>
<td><strong>Volume (Cubic Feet):</strong></td>
<td><strong>5.50612</strong></td>
</tr>
<tr>
<td><strong>CVX Code:</strong> MVX Code:</td>
<td><strong>Depth:</strong></td>
<td><strong>48</strong></td>
</tr>
<tr>
<td><strong>Description:</strong> Rosuvastatin is in a group of drugs called HMG CoA reductase inhibitors, or &quot;statins.&quot; Rosuvastatin reduces levels of &quot;bad&quot; cholesterol (low-density lipoprotein, or LDL) and triglycerides in the blood, while increasing levels of &quot;good&quot; cholesterol (High-density lipoprotein, or HDL).</td>
<td><strong>Height:</strong></td>
<td><strong>91315.2</strong></td>
</tr>
<tr>
<td><strong>Active ingredients:</strong> Rosuvastatin Calcium Tabs</td>
<td><strong>Weight:</strong></td>
<td><strong>408.85</strong></td>
</tr>
</tbody>
</table>

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**FOR GENERIC DRUG PRODUCTS**

- **Orange Book Rating:** AB
- **Brand Name:** Crestor
- **Generic Equivalent for Brand:**

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**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

- **Is product exempt from DSCSA?** Yes
- **DUNS:** 978731527
- **Is product re-packaged?** No
- **Are any waivers granted for product ID/barcode?** No

**ITEM AND PACKAGING INFORMATION**

- **Unit of Sale:** Bottle
- **Weight Lbs.:** 0.062
- **Dimensions (US msmts.):**
  - **Depth:** 1
  - **Height:** 3.526
  - **Width:** 1.562
  - **Volume (Cubic Feet):** 5.50612
- **# Pieces:** 1

**ORDER INFORMATION**

- **What is the NDC selling unit?** 1 Bottle of 90
- **Minimum order quantity:** Yes

**ITEM AND PACKAGING INFORMATION**

- **Item:** Bottle
  - **Box/Carton:** 1.562
  - **Case:** 3.75
  - **Pallet:** 408.85
  - **UPC:** 50357237168900

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**ADDITONAL PRODUCT INFORMATION**

- **Legend Device?** No
- **State Control?** No
- **ARGC reportable?** No
- **Co-Licensed?** No
- **Controlled Substance?** No
- **Schedule No.?** (incl. N for non-narcotic) No
- **Controlled Substance Code:**
  - **Hazardous Material/Cytotoxic Agent?** No
- **Is Item...** Unit of Use
- **If Unit Dose, is item bar coded to unit dose for hospital scanning?** No
- **Is it reverse numbered?** No

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**WHOLESALE USE ONLY:**

- **Vendor #:**
- **Whsl. Code #:**
- **Fineline Code:**

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**PHARMACY ORDER / BILL UNIT**

- **Rx billing unit to pharmacy:**
  - **Each**
  - **Gram**
  - **Milliliter**

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**COST INFORMATION**

- **Product Shape:** CVAL (Biconvex)
- **Product Color:** PINK
- **Product Imprint:** 29
- **Regular Cost Per Unit of Sale:**
  - **$90.55**
- **Invoice Cost (WAC) ($):**
  - **90.55**
- **Federal Excise Tax Per Unit of Sale:**
  - **40**

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*Please provide any additional information on page 2.*
### Standard Pharmaceutical Product Information (Rx Product Only)

**Company Name:** Citron Pharma LLC  
**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  

**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  
**City:** East Brunswick  
**State:** NJ  
**Zip:** 08816  
**Phone Number:** 732-227-1515  
**Fax:** 732-227-1513  

### ADDITIONAL PRODUCT INFORMATION

**Is the Product...**  
**Legend Device?** No  
**State Control?** No  
**ARGOS reportable?** No  
**Co-Licensed?** No  
**Controlled Substance?** No  
**Schedule No.?** (incl. N for non-narcotic) No  
**Is Item...**  
**Unit of Use**  

**Is the Product...**  
**Direct Ship Item**  
**Is it reverse numbered?** No  

**Vendor #:**  
**Whsi. Code #:**  
**Fineline Code:**

### ITEM AND PACKING INFORMATION

**Weight Lbs.** | Dimensions (US msmts.) | Volume (Cube) | # Pieces  
--- | --- | --- | ---  
0.154 | 1 | 3.08 | 1.875 | 5.775 | 1  
1.929 | 7.95 | 3.1 | 6.06 | 149.3487 | 12  
8.88 | 12.8 | 9.06 | 8.86 | 1027.47648 | 48  
601.4 | 48 | 41.46 | 40 | 79603.2 | 3072  
5035723716893 | Case: | | | |

**UPC:**  
**Case:**  
**Carton:**  
**Pallet:**  
**Minimum order quantity:** Yes  
**If Yes, how many of which package type?**  

### ORDER INFORMATION

**What is the NDC selling unit?**  
1 Bottle of 1000  
 Lâm (Write-in, e.g. 1 Box of 10 Vials)  

**Weight Lbs.** | Depth | Height | Width | Volume (Cube) | # Pieces  
--- | --- | --- | --- | --- | ---  
0.154 | 1 | 3.08 | 1.875 | 5.775 | 1  
1.929 | 7.95 | 3.1 | 6.06 | 149.3487 | 12  
8.88 | 12.8 | 9.06 | 8.86 | 1027.47648 | 48  
601.4 | 48 | 41.46 | 40 | 79603.2 | 3072

**UPC:**  
**Case:**  
**Carton:**  
**Pallet:**  
**Minimum order quantity:** Yes  
**If Yes, how many of which package type?**  

### PHARMACY ORDER/BILL UNIT

**Rec. sell unit to customer:**  
(Drug Other Product Information)  

**Regular Cost Per Unit of Sale ($)** | Invoice Cost (WAC) ($) | Federal Excise Tax Per Unit of Sale |  
--- | --- | --- | ---  
0.154 | 1 | 3.08 | 1.875 | 5.775 | 1  
1.929 | 7.95 | 3.1 | 6.06 | 149.3487 | 12  
8.88 | 12.8 | 9.06 | 8.86 | 1027.47648 | 48  
601.4 | 48 | 41.46 | 40 | 79603.2 | 3072

**UPC:**  
**Case:**  
**Carton:**  
**Pallet:**  
**Minimum order quantity:** Yes  
**If Yes, how many of which package type?**

### COST INFORMATION

**As of date:**