

Standard Pharmaceutical Product Information

| | | | ∐ N | iew Item 💹 I | romotion/D | eal [Open | Stock P | ost Launch Cr | nange | | | |
|--|---|--------------------|---|---|---|----------------|------------------|------------------|----------------------|------------------|------------|--|
| PRODUCT INFORMATION | | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS | | | | | | | |
| Manufacturer/Broker Name: Strides | | a. Temper | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | | | |
| Rx Product Name: Calcitriol Capsules 0.25mcg NDA ANDA | | | | | I. Freezer – between -25 and -10 C (-13° – 14° F) | | | | | | | |
| Product ID Number: | | | | | II. Cold – between 2 and 8 C (36° – 46° F) | | | | | | | |
| Serialized? • Yes • No How? • 2D RFID Pallet Case • Item | | | | | III. Cool – between 8 and 15 C (46° – 59° F) | | | | | | | |
| Description: orange, oval capsules, imprinted with 673 | | | | | IV. Controlled Room – between 20 and 25 C (68° – 77° F) | | | | | | | |
| | | | | | | allows fo | or excursion | ns between 1 | 15 and 30 C | (59° – 86° | F) | |
| URL for additional product information: | | | | | V. Excessive Heat – above 40 C (>104° F) | | | | | | | |
| Address: 201 South Main Street | | | | | VI. Other Temperature Range Requirement | | | | | | | |
| City, State, Zip: Lambertville, NJ, 08530 | | | | | (write in) Store < 25 °C (77°F) Do not Freeze | | | | | | | |
| Key Contact: JB Davis | Email: | Sales@Stride | | VII. No Requirement | | | | | | | | |
| Phone Number: (855)-273-0146 | Fax: | (855)-228-948 | b. Contac | b. Contact for temperature excursion questions: | | | | | | | | |
| Is the Product A Direct Ship Item A Drop Ship Item | | | | | Name: Nagesh Majeti Number: 609-773-5004 | | | | | | | |
| a Controlled Drug? Tyes O No | If Yes, Schedule Nu | mber: | | | | | | _ | | | | |
| ARCOS reportable? Yes No Biological? Yes No | | | | | Is this product to be shipped to customers on ice? Yes No Is this product to be shipped to customers on dry ice? Yes No | | | | | | | |
| Co-Licensed? Yes No Repackaged? Yes No | | | | | | | | | | | | |
| a Legend Device? Tyes No | Does the product of | contain DEHP? | Yes 🖸 No | . | | | | - | _ | _ | | |
| Active ingredient, if product contains a drug | | | | | regulation | s for this pro | duct in certa | ain states? | 🔘 *Ye | s 🧿 N | 0 | |
| Country of Origin: | | | | | Special returns requirements for this product? | | | | | | | |
| Harmonization Code Number for Internation | nal Shipping: | | | | | • | • | | _ | | | |
| Is this product a Hazardous Material or Cytotoxic Agent? | | | | | d. Store product upright? | | | | | | | |
| *If | yes, provide addition | nal information | n on page 2. | Protec | t product f | rom light? | C Yes | No No No | Other requi | rements? | * | |
| Attach copy of MATERIAL SAFETY DATA | SHEET (MSDS) and | PACKAGE IN | ISERT | | | | *Please pro | vide additio | nal informat | tion on pa | ge 2. | |
| | | | | ITEM AND | PACKING | INFORMATIO |)N | | | | | |
| ADDITIONAL PRODUCT INFORMATION | | | • | | 1 | | | _ | | | T | |
| Draduct Change 0 1 | Size/Strength/ | Unit of Sale | UPC Code | Mstr. | Inner | Wght. Lbs. | Cube | Case | Dimensions I Item | Pallet | # Cases/ | |
| Product Shape Oval | Form 100's/0.25 mcg | ✓ Bottle | Carac | Shpr. | Case Pk | Casa | 4.470.0000 | | | | Pallet | |
| Product Color Orange | /Capsules | | Case: | (Bottles) | 24 (Bottles) | Case: | 1478.3666 | Depth: | Depth: | Depth: | 33 | |
| Product Imprint 673 | - Capsules | Box Glass Jar | Cartan | (Bottles) | (Botties) | 13.195 | | 13.582 | 1.496 | 47.992 | | |
| Is there a minimum order quantity? Yes No | | Ampule | Carton: | | | Carton: | | Height: | Height: | Height: | | |
| | | I= · | lt a ma . | | | 2.007 | | 10.433 Width: | 2.755 Width: | 41.457 Width: | | |
| If yes, how many? | 4 | U Other: | Item: | | | Item: 0.074 | | | 1.496 | | | |
| Of what package type? | | | | | | 0.074 | | 10.433 | 1.496 | 38.307 | | |
| Case Carton LItem | For Generic Drug Pr | | | | | | | | | | | |
| Shelf life: 24 Months | I. Orange Book: Rating: AB III. Product Color: Orange | | | | III. Brand Name Equivalent: ROCALTROL IV. Generic Name for Brand: Calcitriol Cansules | | | | | | | |
| Initial shelf life at launch (if diff't) | II. Product Color: Orange | | | | IV. Generic Name for Brand: Calcitriol Capsules COST INFORMATION | | | | | | | |
| | | Dunah | ana Allawanaa | | | WATION | 1 | 1 | ı | ı | 1 | |
| Whsl. Code #: | D | Purchase Allowance | | | Distribution Distribution | | Invoice Net Cost | Meric AVAID | Avg Retail | ODD (A) | F T | |
| Fineline Code: Is Item? | Regular Cost (\$) | <u> </u> | OI BB % | OI | ☐ BB ※ | Cost (\$) | (\$) | Mfr's AWP | Price (\$) | SRP (\$) | Excise Tax | |
| offic bose offic of ose | | * | ,, | * | ,,, | | | | | | | |
| If Unit Dose, is item bar coded to unit dose | | | | | | | | | | | | |
| for hospital scanning? O Yes No | EA PPK | | | | | | | | | | | |
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Date: 02.08.14