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

Version 2024 | Introduction Type: | Final Version | Date: 10/21/2026

## PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| Company Name: | CREEKWOOD PHARMACEUTICALS LLC | Application: | ANDA |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 218875 | NDA 505(b) Type: | |
| Medical Device Class, if applicable: | | | |
| DUNS: | 118582565 | | |
| Proprietary Name (If Applicable) and Established Name: | Atomoxetine Capsules USP 100 mg | | |
| Selling Unit NDC: | 82619-121-01 | Unit of Use NDC: 82619-121-01 | UPC: 382619121018 |
| UDI | | CVX Code: | MVX Code: |
| Description: | White opaque body, orange opaque cap, size '0' hard gelatin capsule. Imprinted with '387' on cap and '100' on body in black ink, filled with white to off white powder | | |
| Active Ingredient(s): | Atomoxetine Hydrochloride USP | | |
| URL for Additional Product Information: | | | |
| Address: | 1130 US 46 W | Address 2: Suite 21 | |
| City: | Parsippany | State: NJ | Zip: 07054 |
| Key Contact: | Paul Thomas | Email: | paul@creekwoodpharma.com |
| Phone Number: | 1-732-344-022 | Fax: | |
| Product Therapeutic Classification: | Attention-Deficit/Hyperactivity Disorder (ADHD) | | |

## ADDITIONAL PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| The product is? | | Is the Product… | Direct-Ship Only |
| a legend device? | No | Is the Product… | Unit of Use |
| if yes, enter class # | | Orphan Drug Status | |
| a product kit? | No | | |
| if yes, list NDCs of component parts | | FDA Approval Status | |
| reverse numbered? | No | | |
| co-licensed? | No | Allergens Present | |
| latex-free? | Yes | Not present | |
| preservative-free? | Yes | | |
| correctional institution block? | No | | |
| opioid? | No | | |
| Cannabinoid? | No | Country of Origin | INDIA |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | No | Is this product covered under the Trade Agreements Act (TAA)? | No |
| If Unit Dose, indicate NDC here: | | | |

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| Size: | 21 mm |
| Strength: | 100 mg |
| Dosage Form: | Capsule |
| Product Shape: | Capsule shaped |
| Product Color: | orange (Orange Opaque) |
| Product Imprint: | 387 on cap and 100 on body |

## FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:

II. Generic Equivalent to What Brand?: Strattera

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| | | | |
|---|---|---|---|
| Does supplier meet DSCSA definition of manufacturer? | Yes | GLN: | 850045940003 |
| Is product exempt from DSCSA? | | | |
| If yes, select exemption: | | GCP: | 850045940 |
| 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 | | |
| Has FDA granted waiver/exception/exemption for product? | No | Provide source manufacturer for repackaged product | |
| If yes, attach documentation from FDA. | | | |

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|---|
| x | Item/Each | | 1 | | 00382619121018 | 00382619121018 |
| | Box/Carton/Bundle/Inner Pack | | | | | |
| x | Case | | 60 | | 20382619121012 | |
| x | Pallet | | 5760 | | | |

## SPECIAL HANDLING AND STORAGE REQUIREMENTS*

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

**b. Contact for temperature excursion questions:**

Name: SUJIT SAKPAL

Number: 551-303-9330

Group E-mail: suit@creekwoodpharma.com

**c. Special regulations for product in any states?** No

Special returns requirements for this product? No

**d. Store product (unit of sale) upright?** No

**Protect product (unit of sale) from light?** No

**e. Shelf life:** 24 Months

**Initial shelf life at launch (if different):** 24 Months

## ORDER INFORMATION

**Unit of Sale**

| | |
|---|---|
| x | Bottle |
| | Box/Carton |
| | Ampule |
| | Glass |
| | Tube |
| | Vial Liquid Sgl |
| | Vial Liquid Multi |
| | Vial Powder Sgl |
| | Vial Power Multi |
| | Other: Write In |

**What is the NDC selling unit?** 1 bottle of 30 Tablets

(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?** Yes

**If Yes, how many of which package type?**

| | |
|---|---|
| 60 | Each |
| | Inner/Carton/Pack |
| 1 | Case |

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?** 1 bottle of 30 tablets

(Write-in, e.g. 1 Vial)

**HCPCS J-Code:**

**Rx billing unit to pharmacy:**

| | |
|---|---|
| x | Each |
| | Gram |
| | Milliliter |

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.14 | 1.61 | 1.61 | 3.11 | 8.06 | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | | |
| Case: | 9.54 | 10.03 | 8.46 | 8.07 | 684.77 | 60 |
| Pallet: | 763.11 | 40.15 | 33.85 | 48.42 | 65806.53 | 5760 |

## COST INFORMATION

Regular Cost

Invoice Cost (WAC) ($)

As of date:

## WHOLESALER USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

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:

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

**Version 2024**

**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) | No |
| 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) | No |
| 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: | No |

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

| | |
|---|---|
| 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#

### SDS Hazard Classification

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

| | |
|---|---|
| Does the product have an Aerosol class? If yes, identify | No |
| NFPA Storage Level: | |
| 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 |
| If Yes, is it managed with a pharmacy registry? | |
| Website URL: | |
| Med Guide Required | No |
| Limited Distribution Requirement | No |
| Comments / Details: (For example, iPledge program?) | |
| **REMS:** | No |
| 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 | IT IS NOT A REMS PRODUCT |
| **Registry:** | No |
| Registry Program Contact Name: | Phone: |
| Comments | IT IS NOT A REMS PRODUCT |

### ADD'L STORAGE INFORMATION

Is the Product…

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

### CLASS OF TRADE RESTRICTION:

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

### RETURN INSTRUCTIONS

| | |
|---|---|
| Contact tel. # if product received damaged: | |
| Is product returnable for credit: | |
| URL/Link to returns policy: | https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf |
| 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:

Release DATE

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

**Version 2024**

**FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.**

## Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

- a. EDI
- b. Autofax — Fax Number:
- c. Fax — Fax Number:
- d. Phone only — Phone No.:
- e. Supplier Web Site only — Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #: Name: Direct customer solutions (R & S)

Phone: 1-800-655-7556

## Standard Order Receipt and Processing

**Purchase order daily receipt cut off time by supplier**

Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:

Ships for second day receipt:

Ships regular ground for 3-10 days receipt:

## Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**

PO Receipt cut off time:

Days of week overnight is available:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

**Priority Overnight receipt available:**

PO Receipt Cut off time:

**Saturday Overnight receipt available:**

PO Receipt Cut off time:

Order receipt method: Phone: Phone #: Fax: Fax #: EDI:

Overnight Fees apply:

Other fees apply:

## Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

## Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

## Return Instructions

Contact # if product is 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:

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?