

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

| Version 2021  |   |                  |                              |                |                      | Introduction                          | Туре:                            | Post Launch Change  |   | 4             | Final Version                            |                      |                | Date:                  | 10/19        | 9/2023       |  |
|---|---|------------------|------------------------------|----------------|----------------------|---------------------------------------|----------------------------------|---|---|---------------|--|----------------------|----------------|------------------------|--------------|--------------|--|
|   |   |                  | PRODUCT INFORMA              | TION           |                      |                                       |                                  |   |   |               | SPECIAL HAN                              | DLING AND STOR       | AGE REQUIR     | EMENTS*                |              |              |  |
| Company Name:   | Company Name: Camber Pharmaceuticals. Inc.            |                  |                              |                | Application: ANDA    |                                       |                                  | a. Temperature – Indicate the USP temperature range for t |   |               |  | his product.         |                |                        |              |              |  |
| Application Number for NDA/AN   |   | ., .             | e):                          | 203            | 2682                 |                                       |                                  |   | ui remperati                                      |               | ure Range                                | Controlled Room -    | - between 20 a | and 25 C (68           | ° – 77° F)   |              |  |
| Medical Device Class, if applical                                     |   |                  | ,                            |                |                      |                                       |                                  |   |   |               | J. J |                      |                |                        |              |              |  |
| DUNS:   | 11-856-3719   |                  |                              |                |                      |                                       |                                  |   |   | Other Ter     | nperature Range F                        | Requirement          |                |                        |              |              |  |
| Proprietary Name (If Applicable) a                                    | nd Established Name:                                  | Atomox           | ketine Hydrochloride Capsu   | les, USP 100 m | g                    |                                       |                                  |   |   | (writ         | e in)                                    | •                    |                |                        |              |              |  |
| Selling Unit NDC:   | 31722-720-30  |                  | Unit of Use NDC:             |                | 31722-720-30         | UPC:                                  | 331722                           | 2720304   |   | Notes         |  |                      |                |                        |              |              |  |
| UDI   |   |                  | CVX Code:                    |                |                      | MVX Code:                             |                                  |   |   |               |  |                      |                |                        |              |              |  |
| Description:  | Atomoxetine Hydrochlor                                | ide Capsules. U  | JSP 100 mg                   |                |                      |                                       |                                  |   |   | Is this pro   | duct to be shipped                       | I to customers on id | e?             |                        | No           | 1            |  |
| Is this product to be shipped to customers on dy ice? No              |   |                  |                              |                |                      |                                       |                                  | 1   |   |               |  |                      |                |                        |              |              |  |
| Active Ingredient(s): Atomoxetine                                     |   |                  |                              |                |                      |                                       |                                  |   |   |               |  |                      |                |                        |              |              |  |
| b. Contact for temperature excursion questions:                       |   |                  |                              |                |                      |                                       |                                  |   |   |               |  |                      |                |                        |              |              |  |
| URL for Additional Product Information: www.camberpharma.com          |   |                  |                              |                |                      |                                       | Name: Soma Raju                  |   |   |               |  |                      |                |                        |              |              |  |
| Address:  | 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 |                  |                              |                |                      | Address 2:                            |                                  |   | Number:   |               |  |                      | 732-529-0423   |                        |              |              |  |
| City:   | Piscataway  |                  |                              |                | State:               | NJ                                    |                                  |   |   | Group E-mail: |  |                      |                | somaraju@heterousa.com |              |              |  |
| Key Contact:  |   |                  |                              |                |                      |                                       | customerservice@camberpharma.com |   |   |               |  |                      |                |                        |              | 1            |  |
| Phone Number:   |   |                  |                              |                | 732-562-8788         | 732-562-8788                          |                                  |   | c. Special regulations for product in any states? |               |  |                      | No             |                        |              |              |  |
| Product Therapeutic Classificatio                                     | n: Selec  | ctive norepineph | hrine reuptake inhibitor (SN | RI)            |                      |                                       |                                  |   |   | Special re    | turns requirement                        | s for this product?  |                |                        | No           | 1            |  |
|   |   |                  |                              |                |                      |                                       |                                  |   |   |               |  |                      |                |                        |              | 1            |  |
|   | ADDITIONAL  | PRODUCT INF      | ORMATION                     |                |                      | PRODUCT                               | DESCRI                           | PTION INFORMATION   | d. Store proc                                     | duct (unit of | sale) upright?                           |                      |                |                        | No           |              |  |
| The product is?   |   |                  | Is the Product               | Direct-Ship C  | Dnly                 |                                       | _                                |   |   | Protect p     | roduct (unit of sa                       | le) from light?      |                |                        | No           |              |  |
| a legend device?  | No  |                  | Is the Product               | Unit of Use    |                      | Size:                                 |                                  | 30 ct   | e. Shelf life:                                    |               |  |                      |                |                        | 24           | Months       |  |
| if yes, enter class #   |   |                  | Orphan Drug Status           |                |                      | 5126.                                 |                                  | 50 61   |   | Initial she   | elf life at launch (i                    | f different):        |                |                        |              | Months       |  |
| a product kit?  | No  |                  |                              |                |                      | Strength:                             |                                  | 100 mg  |   |               |  |                      |                |                        |              |              |  |
| if yes, list NDCs of  |   |                  | FDA Approval Status          |                |                      | ouongun                               |                                  | loo ng  |   |               |  | ORDER INFORM         | IATION         |                        |              |              |  |
| component parts   |   |                  |                              |                |                      | Dosage For                            | m:                               | Hard gelatin capsules                                     |   |               |  |                      |                |                        |              |              |  |
| reverse numbered?   | No  |                  |                              |                |                      | -                                     | L                                |   | _   | Unit of Sa    |  |                      | What is the I  |                        | unit?        |              |  |
| co-licensed?  | No  |                  | Allergens Present            |                |                      |                                       | г                                |   | _   |               | Bottle                                   |                      | 1 Bottle of 30 |                        |              |              |  |
| latex-free?   | Yes   |                  |                              |                |                      | Product Sha                           | ape:                             | Capsule   |   |               | Box/Carton                               |                      | (Write-in, e.g | I. 1 Box of 10         | Vials)       |              |  |
| preservative-free?<br>correctional institution block?                 | Yes   |                  |                              |                |                      |                                       | -                                | Draum anagua aon and                                      | -   |               | Ampule<br>Glass                          |                      | Minimum en     |                        |              | Yes          |  |
| opioid?   | No  |                  |                              |                |                      | Product Col                           |                                  | Brown opaque cap and<br>Brown opaque body                 |   |               | Tube                                     |                      | Minimum or     | der quantity           | ſ            | res          |  |
| Cannabinoid?  | No  |                  | Country of Origin            | India          |                      |                                       | -                                |   | -   |               | Vial Liquid Sgl                          |                      |                |                        |              |              |  |
| If Unit Dose, is item bar coded to u                                  |   |                  | obuility of origin           | India          |                      | Product Imp                           | print:                           | 'l' on cap and '111' on body                              |   |               | Vial Liquid Multi                        |                      | If Yes, how r  | nany of whi            | h nackage t  | type?        |  |
| hospital scanning?  |   |                  | Is this product covered u    | under the      |                      |                                       | L                                |   | -   |               | Vial Powder Sql                          |                      |                | Each                   | in puonago i | <b>JP0</b> · |  |
| If Unit Dose, indicate NDC here:                                      |   |                  | Trade Agreements Act (       |                | No                   |                                       |                                  |   | Vial Power Multi                                  |               |  | Pack                 |                |                        |              |              |  |
|   |   |                  |                              | ,              |                      |                                       |                                  |   |   |               | Other: Write In                          |                      |                | Case                   |              |              |  |
| -   |   |                  | FOR GENERIC DRUG PR          | ODUCTS         |                      |                                       |                                  |   |   |               |  |                      |                |                        |              |              |  |
|   |   |                  |                              |                |                      |                                       |                                  |   |   | L             |  |                      |                |                        |              |              |  |
|   |   |                  |                              |                | Au                   | thorized Generic                      | *If Auth                         | norized Generic, other                                    |   |               | PH                                       | ARMACY ORDER         | / BILL UNIT    |                        |              |              |  |
| I. Orange Book Rating:  | AB  |                  |                              |                |                      |                                       | section                          | fields are not applicable                                 | Rec. sell uni                                     | t to custom   | er?                                      |                      | Rx billing un  | it to pharma           | cv:          |              |  |
| I. Generic Equivalent to What Brand?: Strattera                       |   |                  |                              |                |                      |                                       |                                  | Each  |   |               |  |                      |                |                        |              |              |  |
|   |   |                  |                              |                |                      |                                       |                                  |   | (Write-in, e.g. 1 Vial) Gram                      |               |  |                      |                |                        |              |              |  |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Milliliter         |   |                  |                              |                |                      |                                       |                                  |   |   |               |  |                      |                |                        |              |              |  |
|   |   |                  |                              |                |                      |                                       |                                  |   |   |               |  |                      |                |                        |              |              |  |
| Does supplier meet DSCSA defini                                       | tion of manufacturer?                                 |                  | Yes                          | _              | GLN:                 | 0331722000000                         |                                  |   |   |               | ITEM                                     | AND PACKING I        | NFORMATION     |                        |              |              |  |
| Is product exempt from DSCSA?   |   |                  | No                           |                |                      |                                       | _                                |   |   |               |  |                      |                |                        |              |              |  |
| If yes, select exemption:   |   |                  |                              |                | GCP:                 |                                       |                                  |   |   |               | Weight Lbs.                              |                      | ons (US msm    | -                      | Volume       | Saleable #   |  |
| Other exemption - Write in:   |   |                  | No                           |                |                      |                                       |                                  |   |   |               |  | Depth                | Width          | Height                 | (Cube)       | Pieces       |  |
| Is product repackaged?  |   |                  |                              | _              |                      | riginal product                       |                                  |   | Item/Each:  |               | 0.10                                     | 1.75                 | 1.75           | 2.50                   | 7.66         | 1            |  |
| Is product sold by manufacturer's<br>Has FDA granted waiver/exception |   | 2                | Yes<br>No                    |                |                      | irect from mfr?<br>ce manufacturer fo | or ronact                        | kaged product   | Box/Carton/                                       | Bundlo/       |  |                      |                |                        |              |              |  |
| If yes, attach documentation from                                     |   | r                | NO                           |                | Flovide Soul         |                                       | orrepace                         | kageu product   | Inner Pack:                                       | bunule/       |  |                      |                |                        |              |              |  |
| in yes, attach documentation not                                      |   |                  |                              |                |                      |                                       |                                  |   | Case:   |               |  |                      |                |                        |              |              |  |
|   |   | GTIN             | N AND HIBCC PRODUCT I        | NFORMATION     |                      |                                       |                                  |   |   |               | 2.80                                     | 11.00                | 7.50           | 4.00                   | 330.00       | 24           |  |
|   |   |                  |                              |                |                      |                                       |                                  |   | Pallet:   |               |  |                      |                |                        |              |              |  |
| Saleable Unit of Measure  | Saleabl   | e Quantity       | HIBCC                        |                | GTI                  | N-14                                  |                                  | Unit of Use GTIN-14                                       |   |               |  |                      |                |                        |              |              |  |
| X Item/Each   |   | 1                |                              |                | 003                  | 31722720304                           |                                  | 00331722720304  | -   |               |  |                      |                |                        |              |              |  |
| Box/Carton/Bundle/Inner Pack  |   |                  |                              |                |                      |                                       |                                  | COST  | INFORMATION                                       |               | ٧  | VHOLESALE            | R USE ONL      | Y:                     |              |              |  |
| X Case  |   | 24               |                              |                | 203                  | 31722720308                           |                                  |   |   |               |  |                      |                |                        |              |              |  |
| Pallet  | _   |                  |                              |                |                      |                                       |                                  |   | Regular   |               |  |                      | Vendor #:      |                        |              |              |  |
|   |   |                  |                              |                | _                    |                                       | _                                |   | Invoice Cost                                      | (WAC) (\$)    |  | \$71.00              | Whsl. Code     |                        |              |              |  |
|   |   |                  |                              |                |                      |                                       | _                                |   | 1.  |               |  |                      | Fineline Cod   | e:                     |              |              |  |
|   |   |                  |                              |                |                      |                                       | _                                |   | As of date:                                       | L             |  |                      |                |                        |              |              |  |
|   |   |                  |                              |                |                      |                                       |                                  |   |   |               |  |                      |                |                        |              |              |  |
| μ   |   |                  |                              |                |                      |                                       |                                  |   |   |               |  |                      | I              |                        |              |              |  |
| *Please provide any additional inf                                    |   |                  | Attach copy of SAFETY DA     | ATA SHEET (SD  | <li>or non haza</li> |                                       |                                  | T, LABEL AND PHOTO OF P                                   | KODUCT PACK                                       |               |  |                      |                |                        |              |              |  |
|   |   |                  |                              |                |                      | See new p. 3 for                      | r Designa                        | ated Drop Ship Only.                                      |   | Signature     | :  |                      |                |                        |              |              |  |

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

| ·   | nated Drop Ship Only Products, Please Use Page 3   |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|
| MATERIAL H  | 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? C. Contact Hazard? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No   | x       Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No         NFPA Storage Level:       Image: Contact Hazard |  |  |  |  |  |  |
| Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class   | Is the product a NIOSH hazardous drug? No If yes, indicate which: Hazardous Waste Identification   |  |  |  |  |  |  |
| d. Packing Group e. Inhalation Hazard?  | EPA Hazardous Waste Code: Waste Characteristics  |  |  |  |  |  |  |
| Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name  | REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No  |  |  |  |  |  |  |
| c. DOT Hazard Class<br>d. Packing Group<br>e. Inhalation Hazard?<br>Is the product restricted for air shipment? If so, indicate restriction:<br>Passenger   | If Yes, is it managed with a pharmacy registry?<br>Website URL:<br>Med Guide Required<br>Limited Distribution Requirement  |  |  |  |  |  |  |
| Cargo<br>Passenger & Cargo<br>Is this a reportable quantity? No<br>RQ Threshold:  | REMS:     No       REMS Program Manager Name:     Phone:   |  |  |  |  |  |  |
| Is this a marine pollutant? No<br>Is this product shipped utilizing an authorized DOT exception or Special Permit?<br>No (if yes, identify method below)<br>Limited Quantity<br>Consumer Commodity, ORM-D<br>Small Quantity (49 CFR 173.4)  | Supplier Manages REMS registry exclusively:  |  |  |  |  |  |  |
| Special Permit; DOT-SP<br>Special Provision (listed in Column 7 of 49 CFR 172.101);   | Comments   |  |  |  |  |  |  |
| ADD'L STORAGE INFORMATION   | Registry:     No       Registry Program Contact Name:     Phone:       Comments  |  |  |  |  |  |  |
| Controlled Substance? No Controlled Substance Code  | RETURN INSTRUCTIONS  |  |  |  |  |  |  |
| Controlled by State(s)?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:       Image: Control of the state of | Contact tel. # if product received damaged:<br>Is product returnable for credit:<br>URL/Link to returns policy:  |  |  |  |  |  |  |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes   | contact - customerservice@camberpharma.com   |  |  |  |  |  |  |
| Restricted to retail pharmacy only:     No       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No   | Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?  |  |  |  |  |  |  |
| Comments:   |  |  |  |  |  |  |  |
| MISCELLAN   | IEOUS NOTES and/or Image of Product Barcode:   |  |  |  |  |  |  |
|   |  |  |  |  |  |  |  |



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

| Version 2021 FOR DESIGNATED DROP SHIP PRODUCT ONLY - if   | not a designated drop ship, do not complete.   |
|---|--|
| Order Method for Designated Drop Ship Product   | Standard Order Receipt and Processing  |
| Purchase orders may be accepted by:         a. EDI         b. Autofax         c. Fax         d. Phone only         e. Supplier Web Site only         Minimum Order Quantity:         Supplier's Customer Service Number:         Contracted 3PL company / contact #:         Name:         Phone: | 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:   | Overnight and Priority Overnight PO Processing   |
| Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:   | Overnight receipt available:       Image: Comparison of the co |
| Class of Trade Restriction:   | PO Receipt Cut off time:   |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices<br>Restricted to retail pharmacy only:<br>Restricted to hospital, clinics, and physician offices only:<br>Restricted from US territories? (explain in comments)<br>Comments:                      | Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:  |
| Other Data Information Required to Process PO:  | Return Instructions  |
| Patient Procedure Date:   | Contact # if product is received damaged:<br>Is product returnable for credit:<br>URL/Link to returns policy:<br>Special regulations or returns requirements for this product in certain states?<br>If so, which states? Other requirements? Comments?   |
| Miscellaneous Notes:  |  |
|   | ADDITIONAL INFORMATION   |
|   | Is product order for scheduled patient procedure?  |