



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

Version 2024

Introduction Type: Final Version

Date: 12/11/2025

PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Company Name: Camber Pharmaceuticals, Inc.			Application: ANDA												
Application Number for NDA/ANDA/BLA; PMA/510(k): 217761			NDA 505(b) Type: NOT APPLICABLE												
Medical Device Class, if applicable:															
DUNS: 11-856-3719															
Proprietary Name (If Applicable) and Established Name: Spironolactone Tablets, USP 25 mg															
Selling Unit NDC: 31722-094-10		Unit of Use NDC:		UPC: 331722094108											
UDI		CVX Code:		MVX Code:											
Description: Spironolactone Tablets, USP 25 mg															
Active Ingredient(s): Spironolactone, USP															
URL for Additional Product Information: www.camberpharma.com															
Address: 800 Centennial Ave, Suite 1			Address 2: NJ Zip: 08854												
City: Piscataway			Email: customerservice@camberpharma.com												
Key Contact: Customer Service			Fax: 732-562-8788												
Phone Number: 1-866-827-3647			Product Therapeutic Classification: Aldosterone antagonist												
ADDITIONAL PRODUCT INFORMATION						PRODUCT DESCRIPTION INFORMATION									
The product is?			Is the Product... Direct-Ship Only												
a legend device?			Is the Product... Neither												
if yes, enter class #			Orphan Drug Status												
a product kit?															
if yes, list NDCs of component parts															
reverse numbered?			FDA Approval Status												
co-licensed?															
latex-free?			Allergens Present												
preservative-free?			Dairy, Lactose, Casein, Corn, Wheat												
correctional institution block?															
opioid?															
Cannabinoid?															
If Unit Dose, is item bar coded to unit dose for hospital scanning?															
If Unit Dose, indicate NDC here:															
Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/>															
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION									
I. Orange Book Rating: AB						Unit of Sale									
II. Generic Equivalent to What Brand?: Aldactone						What is the NDC selling unit?									
						<input checked="" type="checkbox"/> Bottle									
						Box/Carton									
						Ampule									
						Glass									
						Tube									
						Vial Liquid Sgl									
						Vial Liquid Multi									
						Vial Powder Sgl									
						Vial Powder Multi									
						Other: Write In									
						Minimum order quantity?									
						<input type="checkbox"/> Yes									
						If Yes, how many of which package type?									
						12 Each									
						Inner/Carton/Pack									
						Case									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT									
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes						Rec. sell unit to customer?									
Is product exempt from DSCSA? <input type="checkbox"/> No						Rx billing unit to pharmacy:									
If yes, select exemption: <input type="checkbox"/>						(Write-in, e.g. 1 Vial)									
Other exemption - Write in: <input type="checkbox"/>						<input type="checkbox"/> Each									
Is product repackaged? <input type="checkbox"/> No						<input type="checkbox"/> Gram									
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes						<input type="checkbox"/> Milliliter									
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No															
If yes, attach documentation from FDA.															
GTIN AND HIBCC PRODUCT INFORMATION						ITEM AND PACKING INFORMATION									
Saleable Unit of Measure		RFID tag(Y/N)		Saleable Quantity		GTIN-14		Dimensions (US msrnts.)		Volume (Cube)		Saleable # Pieces			
<input checked="" type="checkbox"/> Item/Each		N		1		00331722094108		Depth		2.6		4.22		28.53	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack		N		12		20331722094102		Width		2.6		5.75		1	
<input checked="" type="checkbox"/> Case								Height							
<input checked="" type="checkbox"/> Pallet															
COST INFORMATION						WHOLESALER USE ONLY:									
Regular Cost						Vendor #:									
Invoice Cost (WAC) (\$)						\$51.45									
As of date: 12/5/2025						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.

See new p. 3 for Designated Drop Ship Only.

*Please provide any additional information on page 2.

Signature:



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen?
- c. Is the product a CA Prop 65 reproductive toxicant?
- d. Does the product label bear a CA Prop 65 warning?

No

No
 No
 No

No
 No

No

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
- d. Packing Group
- e. Inhalation Hazard?

No

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passager & Cargo

Is this a reportable quantity? No

RQ Threshold: No

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#

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: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic
 Inorganic
 Steroid/Androgen

Corrosive
 Oxidizer
 Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

Yes

If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion)

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?
Website URL:

No

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

No

REMS:

REMS Program Manager Name:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name:
Site Enrollment Number assigned by Supplier:

Phone:

DEA #:
NCPDP#:
NPI #:

Comments:

Registry:

Registry Program Contact Name:
Comments:

No

Phone:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?

No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



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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		Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Hours <input type="text"/> Days	
Minimum Order Quantity: <input type="text"/>		Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days	
Supplier's Customer Service Number: <input type="text"/>		Ships same day for next day receipt: <input type="text"/>	
Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>		Ships for second day receipt: <input type="text"/>	
Ships regular ground for 3-10 days receipt: <input type="text"/>			
Expedited Freight Charges or Other Designated Drop Ship Fees:			
Expedited freight fees billed with each order: <input type="text"/>		Overnight and Priority Overnight PO Processing	
Drop Ship service fee billed with each order: <input type="text"/>		Overnight receipt available: <input type="text"/>	
Drop Ship miscellaneous fees billed: <input type="text"/>		PO Receipt cut off time: <input type="text"/>	
Comments: <input type="text"/>		Days of week overnight is available: Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <input type="checkbox"/>	
Class of Trade Restriction:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		Priority Overnight receipt available: <input type="text"/>	
Restricted to retail pharmacy only: <input type="checkbox"/>		PO Receipt Cut off time: <input type="text"/>	
Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/>		Saturday Overnight receipt available: <input type="text"/>	
Restricted from US territories? (explain in comments) <input type="text"/>		PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Fax: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="text"/> Other fees apply: <input type="text"/>	
Comments: <input type="text"/>			
Other Data Information Required to Process PO:			
Patient Procedure Date: <input type="text"/>		Return Instructions	
Physician Name: <input type="text"/>		Contact # if product is received damaged: <input type="text"/>	
Physician/Clinic Phone # <input type="text"/>		Is product returnable for credit: <input type="text"/>	
Physician State License # <input type="text"/>		URL/Link to returns policy: <input type="text"/>	
Physician/Clinic DEA #: <input type="text"/>		Special regulations or returns requirements for this product in certain states? <input type="text"/>	
Physician/Clinic Specialty: <input type="text"/>		If so, which states? Other requirements? Comments? <input type="text"/>	
Miscellaneous Notes: <input type="text"/>			
ADDITIONAL INFORMATION			
Is product order for scheduled patient procedure? <input type="text"/>			
Is product order for restocking purposes? <input type="text"/>			