



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

Version 2021 Introduction Type:  Post Launch Change  Final Version Date:

PRODUCT INFORMATION	
<b>Company Name:</b>	Camber Pharmaceuticals, Inc.
<b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b>	202910
<b>Medical Device Class, if applicable:</b>	
<b>DUNS:</b>	11-856-3719
<b>Proprietary Name (If Applicable) and Established Name:</b>	Irbesartan Tablets, USP 300 mg
<b>Selling Unit NDC:</b>	31722-731-30
<b>Unit of Use NDC:</b>	31722-731-30
<b>UPC:</b>	331722731300
<b>UDI</b>	
<b>CVX Code:</b>	
<b>MXV Code:</b>	
<b>Description:</b>	Irbesartan Tablets, USP 300 mg
<b>Active Ingredient(s):</b>	Irbesartan, USP
<b>URL for Additional Product Information:</b>	<a href="http://www.camberpharma.com">www.camberpharma.com</a>
<b>Address:</b>	800 Centennial Ave, Suite 1
<b>City:</b>	Piscataway
<b>Key Contact:</b>	Customer Service
<b>Phone Number:</b>	1-866-827-3647
<b>Product Therapeutic Classification:</b>	Angiotensin II receptor blocker (ARB)

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Other Temperature Range Requirement (write in)	<input type="text"/>
Notes	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
<b>b. Contact for temperature excursion questions:</b>	<b>Name:</b> <input type="text" value="Soma Raju"/>
	<b>Number:</b> <input type="text" value="732-529-0423"/>
	<b>Group E-mail:</b> <input type="text" value="somaraju@heterousa.com"/>
<b>c. Special regulations for product in any states?</b>	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	<input type="checkbox"/> No
<b>e. Shelf life:</b>	<b>Protect product (unit of sale) from light?</b> <input type="checkbox"/> No
<b>Initial shelf life at launch (if different):</b>	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
<b>The product is?</b> a legend device? <input type="checkbox"/> No if yes, enter class # <input type="text"/> a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> Yes preservative-free? <input type="checkbox"/> Yes correctional institution block? <input type="checkbox"/> No opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> If Unit Dose, indicate NDC here: <input type="text"/>	<b>Is the Product... Direct-Ship Only</b> <b>Is the Product... Unit of Use</b> <b>Orphan Drug Status</b> <b>FDA Approval Status</b> <b>Allergens Present</b> <b>Country of Origin</b> <input type="text" value="India"/> <b>Is this product covered under the Trade Agreements Act (TAA)?</b> <input type="checkbox"/> No
	<b>Size:</b> <input type="text" value="30 ct"/> <b>Strength:</b> <input type="text" value="300 mg"/> <b>Dosage Form:</b> <input type="text" value="Tablet"/> <b>Product Shape:</b> <input type="text" value="Biconvex, capsule"/> <b>Product Color:</b> <input type="text" value="White to off white"/> <b>Product Imprint:</b> <input type="text" value="Debossed with '160' on one side and 'H' on the other side"/>

ORDER INFORMATION	
<b>Unit of Sale</b>	<b>What is the NDC selling unit?</b>
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 30 Tablets"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	<b>Minimum order quantity?</b> <input type="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	<b>If Yes, how many of which package type?</b>
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> Case

FOR GENERIC DRUG PRODUCTS	
<b>I. Orange Book Rating:</b>	<input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic <small>*If Authorized Generic, other section fields are not applicable</small>
<b>II. Generic Equivalent to What Brand?:</b>	<input type="text" value="Avapro"/>

PHARMACY ORDER / BILL UNIT	
<b>Rec. sell unit to customer?</b>	<b>Rx billing unit to pharmacy:</b>
<input type="text"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
<b>Does supplier meet DSCSA definition of manufacturer?</b>	<input type="checkbox"/> Yes
<b>Is product exempt from DSCSA?</b>	<input type="checkbox"/> No
<b>If yes, select exemption:</b>	<input type="text"/>
<b>Other exemption - Write in:</b>	<input type="text"/>
<b>Is product repackaged?</b>	<input type="checkbox"/> No
<b>Is product sold by manufacturer's exclusive distributor?</b>	<input type="checkbox"/> Yes
<b>Has FDA granted waiver/exception/exemption for product?</b>	<input type="checkbox"/> No
<b>If yes, attach documentation from FDA.</b>	<input type="text"/>
<b>GLN:</b>	<input type="text" value="0331722498975"/>
<b>GCP:</b>	<input type="text"/>
<b>If yes, was original product purchased direct from mfr?</b>	<input type="checkbox"/>
<b>Provide source manufacturer for repackaged product</b>	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.07	1.5	1.5	2.55	5.74	1
<b>Box/ Carton/ Bundle/ Inner Pack:</b>						
<b>Case:</b>	2.15	10	6.75	4.25	286.88	24
<b>Pallet:</b>						

GTIN AND HIBCC PRODUCT INFORMATION				
<b>Saleable Unit of Measure</b>	<b>Saleable Quantity</b>	<b>HIBCC</b>	<b>GTIN-14</b>	<b>Unit of Use GTIN-14</b>
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722731300"/>	<input type="text" value="00331722731300"/>
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	<input type="text" value="24"/>		<input type="text" value="20331722731304"/>	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
<b>Regular Cost</b>	<input type="text"/>	<b>Vendor #:</b>	<input type="text"/>
<b>Invoice Cost (WAC) (\$)</b>	<input type="text" value="\$13.34"/>	<b>Whsl. Code #:</b>	<input type="text"/>
<b>As of date:</b>	<input type="text" value="2/7/2019"/>	<b>Fineline Code:</b>	<input type="text"/>



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

Version 2021

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 NFPA Storage Level:  No  
 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   
 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

**Registry:**  No

Registry Program Contact Name:  Phone:   
 Comments

### 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:

### 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:



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