



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Product Post Launch Change

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	202910
DUNS:	82-667-4775
Proprietary Name (if Applicable) and Established Name:	Irbesartan Tablets 75MG 30CT
Selling Unit NDC:	31722-729-30
Individual Unit NDC:	31722-729-30
UPC:	331722729307
UDI	NA
CVX Code:	
MVX Code:	NA
Description:	Capsule shaped white with the upper embossed with '158' and the lower embossed with 'H'
Active Ingredient(s):	Irbesartan
URL for Additional Product Information:	www.camberpharma.com
Address:	1031 Centennial Avenue
City:	Piscataway
State:	NJ
Zip:	08854
Key Contact:	Customer Service
Email:	customerservice@camberpharma.com
Phone Number:	732-529-0430
Fax:	732-562-8788
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	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"/>
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. Contact for temperature excursion questions:	Name: <input type="text" value="Soma Raju"/>
Number:	<input type="text" value="732-529-0423"/>
Group E-mail:	<input type="text" value="somaraju@heterousa.com"/>
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only	<input type="checkbox"/>
Is the Product... Unit of Use	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text" value="India"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No

PRODUCT DESCRIPTION INFORMATION	
Size:	<input type="text" value="10"/>
Strength:	<input type="text" value="75 mg"/>
Dosage Form:	<input type="text" value="Oral Capsule"/>
Product Shape:	<input type="text" value="capsule"/>
Product Color:	<input type="text" value="white"/>
Product Imprint:	<input type="text" value="158/H"/>

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

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<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	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	<input type="text"/>
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.05		2.1	1.5		
Case:	1.75	10	4.5	6.5	0.169	24
Pallet:						4416
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION					
Serialized?	Level	Saleable Unit		Quantity	GTIN-14
		Item	Unit		
<input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/>	1	00331722729307
If not, when?	<input type="checkbox"/> Case	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/>	24	20331722729301
Items aggregated?	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	\$10.54	Whsl. Code #:	<input type="text"/>
Federal Excise Tax Per Unit of Sale	<input type="text"/>	Fineline Code:	<input type="text"/>
As of date:	<input type="text"/>		

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 Information (Page 2)

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?
 Does the product label bear a CA Prop 65 warning?

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 or IATA? No

(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?

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

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#

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No
 If yes, indicate which:

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 No

Restricted to retail pharmacy only: Yes

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

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?
 If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: NA

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

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

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

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #: No
 PCPDP #: No
 NPI #: No

Comments

Registry: No
 Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 732-529-0430

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:



Standard Pharmaceutical Product Information (Page 3)

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"/> Yes b. Autofax <input type="checkbox"/> No Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Yes Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> No Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> No Site Address: <input type="text"/> Minimum Order Quantity: <input type="text" value="case pack"/> Supplier's Customer Service Number: <input type="text" value="732-529-0430 x466 x465 x467 x470"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text" value="2:30PM"/> Eastern Shipping lead time of PO: <input type="text" value="24/48"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="checkbox"/> No Drop Ship service fee billed with each order: <input type="checkbox"/> No Drop Ship miscellaneous fees billed: <input type="checkbox"/> No Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> Yes PO Receipt cut off time: <input type="text" value="2:30PM"/> Eastern Days of week overnight is available: <input checked="" type="checkbox"/> Monday <input checked="" type="checkbox"/> Tuesday <input checked="" type="checkbox"/> Wednesday <input checked="" type="checkbox"/> Thursday <input checked="" type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text" value="2:30PM EST"/>
Class of Trade Restriction:	Saturday Overnight receipt available:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> No Restricted to retail pharmacy only: <input type="checkbox"/> Yes Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: <input type="text"/>	Saturday Overnight receipt available: <input type="checkbox"/> No PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="checkbox"/> No Phone #: <input type="text"/> Fax: <input type="checkbox"/> Yes Fax #: <input type="text" value="732-562-8788"/> EDI: <input type="checkbox"/> Yes Overnight Fees apply: <input type="checkbox"/> Yes Other fees apply: <input type="checkbox"/> No
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" value="732-529-0430"/> Is product returnable for credit: <input type="checkbox"/> Yes URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes 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"/> No Is product order for restocking purposes? <input type="checkbox"/> No