



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Product Post Launch Change Other

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 300MG 90CT |
| Selling Unit NDC: | 31722-731-90 |
| Individual Unit NDC: | 31722-731-90 |
| UPC: | 331722731904 |
| UDI | NA |
| CVX Code: | |
| MVX Code: | NA |
| Description: | Capsule shaped, white with the upper embossed with '160' 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 |
| Phone Number: | 732-529-0430 |
| Email: | customerservice@camberpharma.com |
| 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="90"/> |
| Strength: | <input type="text" value="300 mg"/> |
| Dosage Form: | <input type="text" value="Oral solid tablet"/> |
| Product Shape: | <input type="text" value="capsule"/> |
| Product Color: | <input type="text" value="white"/> |
| Product Imprint: | <input type="text" value="160/H"/> |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 case 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" value="24"/> Each |
| <input type="checkbox"/> Vial Powder Multi | <input type="text"/> |
| <input type="checkbox"/> Other: Write In | <input type="text"/> |
| | <input type="text"/> |
| | <input type="text"/> |

| 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 <input checked="" type="checkbox"/> No |
| Is product exempt from DSCSA? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| If yes, select exemption: | <input type="text"/> |
| Other exemption - Write in: | <input type="text"/> |
| Is product repackaged? | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| Is product sold by manufacturer's exclusive distributor? | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| Has FDA granted waiver/exception/exemption for product? | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| GLN: | <input type="text"/> |
| If Yes, was original product purchased direct from mfr? | <input type="checkbox"/> |
| If yes, attach documentation from FDA. | <input type="text"/> |

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width | | |
| Item: | 0.15 | | 3.6 | 1.1 | | |
| Box/Carton/Bundle/Inner Pack: | 4.05 | 11.5 | 4.5 | 7.11 | 0.212 | |
| Case: | 4.05 | 11.5 | 4.5 | 7.11 | 0.212 | 24 |
| Pallet: | | | | | | 3072 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | | | | |
|-------------------------------------|----------------------|-------------------------------------|-------------------------------------|------------------------------|-------------------------------------|--------------------------|----------|----------------|--|
| Serialized? | If not, when? | Items aggregated? | Level | | Saleable Unit | | Quantity | GTIN-14 | |
| | | | x | Item | x | Unit | | | |
| <input checked="" type="checkbox"/> | <input type="text"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | Box/Carton/Bundle/Inner Pack | <input type="checkbox"/> | <input type="checkbox"/> | 1 | 00331722731904 | |
| | | | <input checked="" type="checkbox"/> | Case | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 24 | 20331722731908 | |
| | | | <input type="checkbox"/> | Pallet | <input type="checkbox"/> | <input type="checkbox"/> | | | |
| | | | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | | | |
| | | | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | | | |
| | | | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | | | |
| | | | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | | | |
| | | | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------------------|----------------------|---------------------|----------------------|
| Regular Cost | <input type="text"/> | Vendor #: | <input type="text"/> |
| Invoice Cost (WAC) (\$) | \$40.00 | 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:

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:

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"/> 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 |
| Class of Trade Restriction: | |
| 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"/> | |
| 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 |