

## **Standard Pharmaceutical Product Information (Rx Product Only)**

					Introduc	tion Type:	Post Launch Change		Final Version			Date:	4/17	/2017
			PRODUCT INFORMA	TION					SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	r -	
Company Name:	Camber Pharmaceuti	cals				Application:	ANDA	a. Temperature – Indio	ate the USP temper	ature range	for this prod	uct.		
Application Number for NDA	ANDA/BLA (drug);	PMA/510(k)(med device)	):	202910					ature Range				en 20 and 25	C (68° – 77° ł
-	82-667-4775							Other Te	emperature Range Re	auirement				
Proprietary Name (If Applicab		Name: Irbesarta	n 300MG/30CT						rite in)	4				1
	31722-731-30		Individual Unit NDC:	31722-731-3	30 L	PC: 331722731	1300	·						-
UDI	NA		CVX Code:		MVX Co	de: NA		Is this pr	oduct to be shipped to	o customers	on ice?		No	_
Description:	Capsule shaped, whit	e, with the upper emboss	ed with '160' and the lower e	mbossed with 'H'				Is this pr	oduct to be shipped to	o customers	on dry ice?		No	-
Active Ingredient(s):		Irbesartan						b. Contact for tempera Name:	ature excursion que	stions:	Soma Raju			
URL for Additional Product In	formation:	www.camberpharma.com	n					Number	:		732-529-04	23		
	1031 Centennial Ave	nue			Address 2:			Group E	-mail:		somaraju@h	eterousa.com	n	
City:	Piscataway			State:	NJ	Zip:	08854							
	Customer Service Email: customerservice@camberpharma.com				ma.com	c. Special regulations for product in any states? No						_		
Phone Number:	732-529-0430 Fax:			732-562-8788			Special	returns requirements f	or this produ	ct?		No	-	
Product Therapeutic Classific	cation:													
	L PRODUCT INFORM		1		PRODUCT DE	SCRIPTION INFOR	RMATION	d. Store product (unit	of sale) upright? product (unit of sale	) from light	2		No No	-
					TROBUGT DE				product (unit of sale	;) nom light				
Is the Product a legend device?		No						e. Shelf life:	nelf life at launch (if o	1: <i>46</i> 4) -			24	Months Months
reverse numbered?		No		Size:	30			initial sh	ien ine at iaunch (ir d	unterent):				Months
co-licensed?		No							(	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only		Strength:	300	mg								
Is the Product		Unit of Use		Dosage For	m: Ora	solid tablet		Unit of S	Sale		What is the	NDC selling	unit?	
				Dosugeron		Solid tablet			Bottle		1 box of 24			
If Unit Dose, is item bar coded	d to unit dose for hosp	ital scanning?						x	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate ND				Product Sha	ape: cap	sule shaped			Ampule Glass			der quantity		Yes
II UNIT DOSE NDC, INdicate ND	C nere:								Tube		winimum o	rder quantity	1	res
Country of Origin		India		Product Col	lor: whit	e			Vial Liquid Sql					
, ,	4h a Tao da Aaraa araa ata	A = + /TA A)2		Product Imp	orint: 160				Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
Is this product covered under t	the trade Agreements	No No		Froduct imp	100	/П			Vial Powder Sql			Each		
									Vial Power Multi			Inner/Cartor	/Pack	
									Other: Write In		24	Case		
			FOR CENERIC DRUC BR	ODUCTS					Other. White III		24	ouoo		
			FOR GENERIC DRUG PR	ODUCTS						]	24	ouoo		
			FOR GENERIC DRUG PR		thorized Generic	*If Authoriz	ed Generic, other section			MACY ORD	ER / BILL UNI			
L Orange Book Pating	AB		FOR GENERIC DRUG PR		thorized Generic		ed Generic, other section not applicable	Rec. sell unit to custo	PHAR	RMACY ORD	ER / BILL UN	T	2017	
	AB	Avapro	FOR GENERIC DRUG PR		thorized Generic			Rec. sell unit to custo	PHAR	RMACY ORD		T nit to pharm	acy:	
I. Orange Book Rating:		Avapro	FOR GENERIC DRUG PR		thorized Generic			Rec. sell unit to custo	PHAR	] RMACY ORD	ER / BILL UN	T	acy:	
			FOR GENERIC DRUG PR	Aut	thorized Generic				PHAR	RMACY ORD	ER / BILL UN	T nit to pharm Each	acy:	
II. Generic Equivalent to What	t Brand?:	DRUG SUPP	LY CHAIN SECURITY ACT (	DSCSA) INFORMATION	thorized Generic				PHAR mer?	]	ER / BILL UN	T <b>hit to pharm</b> Each Gram Milliliter	acy:	
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## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

le this preduct (sheel, all that apply).	
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive
Is the product a CA Prop 65 reproductive toxicant?	Ovidizer
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:
d. Does this product require special clean-up instructions? No	
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?
e. Does the product contain DEHP? No	If yes, indicate which:
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	Hazardous Waste Identification
c. DOT Hazard Class	EPA Hazardous Waste Code: NA
d. Packing Group	
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS
Passenger	Is there a REMS on this product? No
Cargo	If Yes, is it managed with a pharmacy registry?
Passenger & Cargo	Website URL:
Is this a reportable quantity? No RQ Threshold:	Comments / Details: (For example, iPledge program?)
Is this a marine pollutant? No	Comments / Details. (For example, inledge program?)
Is this a manne political is a manne political is the pol	
No (if yes, identify method below)	REMS:
Limited Quantity	REMS Program Manager Name: Phone:
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No
Special Permit; DOT-SP	Provider Name:
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No
SP#	by Supplier: PCPDP #: No
	NPI#: No
ADD'L STORAGE INFORMATION	· · · · · · · · · · · · · · · · · · ·
Is the Product	Comments
Controlled Substance? No	
Controlled by State(s)? No	Registry: No
ARCOS Reportable? No	Registry Program Contact Name: Phone:
Schedule No. (inc. N for non-narcotic)	Comments
Controlled Substance Code	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS
If yes, indicate which:	
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@camberpharma.com
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states? No
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?
Restricted from US territories? (explain in comments) No	
Comments:	
oommonia.	
MISCELLA	NEOUS 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:       Autofax       Yes         b. Autofax       No       Fax Number:         c. Fax       Yes       Fax Number:         d. Phone only       No       Phone No.:         e. Supplier Web Site only       No       Site Address:         Minimum Order Quantity:       case pack       732-529-0430 x466 x465 x467 x470         Contracted 3PL company / contact #:       Name:       Phone:	Purchase order daily receipt cut off time by supplier         Cut off time:       2:30PM       Eastern         Shipping lead time of PO:       24/48       Hours       Days         Ships same day for next day receipt:       No       No         Ships for second day receipt:       No       No         Ships regular ground for 3-10 days receipt:       Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:       No         Drop Ship service fee billed with each order:       No         Drop Ship miscellaneous fees billed:       No         Comments:       Image: No         Comments:       Image: No         Class of Trade Restriction:         No         Restricted to retail pharmacy, hospitals, clinics and physician offices         No       Yes         Restricted to nospital, clinics, and physician offices only:       No         Restricted from US territories? (explain in comments)       No	Overnight receipt available:       Yes         PO Receipt cut off time:       2:30PM       Eastern         Days of week overnight is available:       X       Monday         X       Tuesday       Wednesday         X       Thursday       Friday         Priority Overnight receipt available:       Yes         PO Receipt Cut off time:       2:30PM EST         Saturday Overnight receipt available:       No         PO Receipt Cut off time:       No         Order receipt method:       Phone:       No         Fax:       Yes       Fax #:
Comments:	rax.     res     rax #.     res       EDI:     Yes       Overnight Fees apply:     Yes       Other fees apply:     No
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is received damaged:       732-529-0430         Is product returnable for credit:       Yes         URL/Link to returns policy:
	ADDITIONAL INFORMATION