

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

Version 2024						Introduction ³	Type:	New Item		x Final Version			Date:	11/19	/2025
			PRODUCT INFORMA	TION						SPECIAL HAI	NDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN	DA/BLA; PMA/510	D(k): 2	12975			NDA 505(b) Type	e: NO	OT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat															
DUNS:	11-856-3719								7	Other Temperature Range	Requirement	Excursions	permitted to 1	5° to 30°C (59	9° to 86°F)
Proprietary Name (If Applicable) a	31722-297-30	ame: Ir	matinib Mesylate Tablets 400 mg Unit of Use NDC:		31722-297-30	UPC:	33172229	7004		(write in) Notes					
Selling Unit NDC: UDI	31122-291-30		CVX Code:		31722-297-30	MVX Code:	33172229	301	+	Notes					
Description:	Imatinib Mesylate	Tableta 400 mm							I I	Is this product to be shippe		2		No	
Description:	IIIIaliiiib iviesylale	e Tablets 400 mg								Is this product to be shippe				No	
Active Ingredient(s): Imatinib mesylate															
b. Contact for temperature excursion questions:															
URL for Additional Product Inform		www.camberpl	narma.com			Address 2:				Name:		Soma Raju			
Address: City:	800 Centennial A Piscataway	ive, Suite 1			State:	NJ	7:m. 00	9054		Number: Group E-mail:		732-529-042	23 neterousa.com		
Key Contact:	Customer Service	е			Email:	-	Zip: 08854 stomerservice@camberpharma.com			Group E-mail.		Somarajuwi	ieterousa.com	<u>u</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regulations for product in any states?						
Product Therapeutic Classification	n:	Selective kinas	se inhibitor							Special returns requiremen	its for this product?			No	
_					_										
	ADDIT	IONAL PRODUC	T INFORMATION			PRODUCT	DESCRIPTI	ON INFORMATION	d. Store prod	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only					Protect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30	ct	e. Shelf life:					24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				400	mg		Initial shelf life at launch	(if different):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:	400	ilig			ORDER INFORM	MATION			
component parts						Dosage For	Filn	n coated tablet							
reverse numbered?		No				Dosage For	m:			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 3			
latex-free? preservative-free?		Yes				Product Sha		al, biconvex scored, el edged		Box/Carton Ampule		(Write-in, e.	g. 1 Box of 10) Vials)	
correctional institution block?		No					\A/b	ite to off white		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				Product Col	lor:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	Debo	ssed with 'H' on one side and '4'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	ınit dose for						on an	e outer side with accretine		Vial Liquid Multi			many of whi	ch package t	ype?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No					Vial Powder Sgl Vial Powder Mult		24	Each Inner/Carton	/Pack	
II Offit Bose, indicate NBC fiere.			Trade rigidements riot (1	701):	140					Other: Write In			Case	/I dok	
FOR GENERIC DRUG PRODUCTS							-								
												_			
				_	Au	thorized Generic		red Generic, other ds are not applicable			HARMACY ORDER				
I. Orange Book Rating:	AB	01					Section lie	us are not applicable	Rec. sen unit to customer?						
II. Generic Equivalent to What Brand?: Gleevec							(Write-in, e.g. 1 Vial) Each								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Write-in, e.g. 1 Vial) Gram HCPCS J-Code: Milliliter															
													-		
Does supplier meet DSCSA definit	tion of manufactu	irer?	Yes No	-	GLN:	0331722498975				ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			INU						1						
If yes, select exemption: Other exemption - Write in:					GCP:					Weight Lbs.	Dimens	ions (US msn Width		Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes, was or	iginal product pur	rchased		Item/Each:	244			Height		
Is product sold by manufacturer's	exclusive distrib	utor?	Yes	1	direct from m					0.14	1.72	1.72	3.3	9.76	1
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	or repackag	ed product	Box/Carton/B	undle/					
If yes, attach documentation from	m FDA.								Inner Pack:						
			GTIN AND HIBCC PRODUCT IN	FORMATION					Case:	3.85	10.75	7.75	4.25	354.08	24
									Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	U	nit of Use GTIN-14							
II		Quantity			000	04700007004	0.0	0004700007004							
x Item/Each Box/Carton/Bundle/Inner Pack	N	1			003	31722297301	00	0331722297301		COST INFORMATION			WHOLESALE	R USE ONL	Y:
X Case	N	24			203	31722297305									
Pallet									Regular Cost			Vendor #:			
									Invoice Cost	(WAC) (\$)	\$125.00	Whsl. Code			
									As of date:	9/16/2025		Fineline Co	de:		
									As or date:	0/10/2020		1			
									<u> </u>			<u> </u>			
			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza	rd letter, PACKAGE	E INSERT, L	ABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE.					
*Please provide any additional info	ormation on naga					C 2 f	. Daaissassas	l Dron Shin Only		Cianatura					



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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? No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:						
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	Is the product a NIOSH hazardous drug? If yes, indicate which: Group 1 items (antineoplastic)						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: Phone: DEA #: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: Is product returnable for credit: RETURN INSTRUCTIONS 1-866-827-3647 Yes						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?						
Comments:							
	OUS NOTES and/or Image of Product Barcode:						
Avoid direct contact of crushed tablets with the skin or mucous membranes. If such contact occurs, wash	thoroughly as outlined in the references.						



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Purchase order ally receipt cut off time by supplier a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing					
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier					
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No. Expedited freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:					
d. Phone only e. Suppler Web Site only Site Address: Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Days of week overnight for ceipt: Days of week overnight for ships for ceipt files: Days of week overnight for ships for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days								
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