

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

Version 2024						Introduction Ty	pe: New Item	<b>X</b>	Final Version			Date:	11/19	9/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Novadoz Pharma	ceuticals, LLC				Application	n: ANDA	a. Temperature – Ir	ndicate the USP tempe	erature range for t	his product.			
Application Number for NDA/AN			4			NDA 505(b) Type:	<u> </u>		perature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applica		,												
DUNS:	081109687							Othe	r Temperature Range F	Requirement	NA			
Proprietary Name (If Applicable)	and Established Na	ame: Nilotin	ib Capsules 200 mg 112 (4)	x 28)	•			T	(write in)					
Selling Unit NDC:	72205-239-64		Unit of Use NDC:				372205239647	Note	S					
UDI			CVX Code:			MVX Code:								
Description:	Nilotinib 200 mg	capsules are light yell	ow opaque colour body and	light yellow opa	que colour cap	imprinted with "MN3"	with black ink.	Is thi	is product to be shipped	d to customers on i	ce?			1
		, , ,				•			is product to be shipped					
Active Ingredient(s):		Nilotinib Hydrochlor	ide sesquihydrate					1						-
									perature excursion que	estions:				
URL for Additional Product Inform								Nam			Mr. M. Ram			
Address:	20 Duke Road				01-1-		Suite A	Num			8790111773			
City:	Piscataway				State: Email:		Zip: 08854	Grou	ıp E-mail:		cgaf2@ms	nlabs.com		
Key Contact: Phone Number:	908-360-1500				Fax:	Sales@novadoz	onarma.com	a Special regulation	ons for product in any	ctotoc?			No	1
Product Therapeutic Classification					- I ux.								No	
Product Therapeutic Classification	on:							Spec	cial returns requirement	is for this product?			INO	
	ADDITI	ONAL PRODUCT IN	FORMATION			PPODUCT DE	SCRIPTION INFORMATION	d Store product (u	nit of calo) unright?				No	1
	ADDITI	ONAL PRODUCT IN		B:		PRODUCT DI	SCRIFTION INFORMATION		nit of sale) upright?					]
The product is?			Is the Product	Direct-Ship C	Only		11011 00		ect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	112 (4 x 28)	e. Shelf life:		· · · · · · · · · · · · · · · · · · ·			24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				200 mg	Initia	al shelf life at launch (	ir airrerent):			24	Months
if yes, list NDCs of		INU	FDA Approval Status			Strength:	200 Hig			ORDER INFORM	MATION			
component parts			1 DA Approvar otatus				Capsules							
reverse numbered?		No				Dosage Form:	Сарошоо	Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 carton of 4	blister packs	(4x28)	
latex-free?		Yes				Product Shape	Capsule	X	Box/Carton		(Write-in, e.	g. 1 Box of 1	) Vials)	
preservative-free?		Yes				Froduct Snap	•		Ampule					
correctional institution block?		No				Product Color	Light yellow		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri	nt: MN3		Vial Liquid Sgl					
If Unit Dose, is item bar coded to hospital scanning?	unit dose for					•			Vial Liquid Multi Vial Powder Sql				ch package	type?
			Is this product covered u	inger the							1 1	Each		
If Unit Dogo indicate NDC here:		72205 220 64			No							Innor/Corton	/Dook	
If Unit Dose, indicate NDC here:		72205-239-64	Trade Agreements Act (		No				Vial Power Multi			Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:		72205-239-64	Trade Agreements Act (*	TAA)?	No							Inner/Carton Case	/Pack	
If Unit Dose, indicate NDC here:		72205-239-64		TAA)?	No				Vial Power Multi				/Pack	
If Unit Dose, indicate NDC here:		72205-239-64	Trade Agreements Act (*	TAA)?		uthorized Generic	If Authorized Generic other		Vial Power Multi Other: Write In	IARMACY ORDER			/Pack	
	ĀR	72205-239-64	Trade Agreements Act (*	TAA)?			If Authorized Generic, other section fields are not applicable	Pec sell unit to cur	Vial Power Multi Other: Write In	IARMACY ORDER	/ BILL UNIT	Case		
I. Orange Book Rating:	AB		Trade Agreements Act (*	TAA)?				Rec. sell unit to cu	Vial Power Multi Other: Write In	IARMACY ORDER		Case		
		72205-239-64 Tasigna	Trade Agreements Act (*	TAA)?					Vial Power Multi Other: Write In  PH stomer?	IARMACY ORDER	/ BILL UNIT	Case  nit to pharma Each		
I. Orange Book Rating:		Tasigna	Trade Agreements Act (	TAA)?	Au			(Write-in, e.g. 1 Via	Vial Power Multi Other: Write In  PH stomer?	IARMACY ORDER	/ BILL UNIT	Case  nit to pharma Each Gram		
I. Orange Book Rating:		Tasigna	Trade Agreements Act (*	TAA)?	Au				Vial Power Multi Other: Write In  PH stomer?	IARMACY ORDER	/ BILL UNIT	Case  nit to pharma Each		
I. Orange Book Rating:	and?:	Tasigna  DRUG SUPPL	Trade Agreements Act (	TAA)?	Au			(Write-in, e.g. 1 Via	Vial Power Multi Other: Write In  PH stomer?	IARMACY ORDER	/ BILL UNIT	nit to pharma Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	Tasigna  DRUG SUPPL	Trade Agreements Act (  FOR GENERIC DRUG PR  LY CHAIN SECURITY ACT (	TAA)?	Au			(Write-in, e.g. 1 Via	Vial Power Multi Other: Write In  PH stomer?	]	/ BILL UNIT	nit to pharma Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra  Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	Tasigna  DRUG SUPPL	Trade Agreements Act (  FOR GENERIC DRUG PR  LY CHAIN SECURITY ACT (  Yes	TAA)?	RMATION GLN:	8904159670843		(Write-in, e.g. 1 Via	Vial Power Multi Other: Write In  PH stomer?	I AND PACKING II	/ BILL UNIT Rx billing u	nit to pharma Each Gram Milliliter	асу:	Saleable#
I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	Tasigna  DRUG SUPPL	Trade Agreements Act (  FOR GENERIC DRUG PR  LY CHAIN SECURITY ACT (  Yes	TAA)?	Au			(Write-in, e.g. 1 Via	Vial Power Multi Other: Write In  PH stomer?	I AND PACKING II	/ BILL UNIT	nit to pharma Each Gram Milliliter		Saleable #
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# **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

### Version 2024 For Designated Drop Ship Only Products, Please Use Page 3

IV	IATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):							
a. Cytotoxic?	Yes	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?	No	Inorganic	Oxidizer				
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard				
, , , , , , , , , , , , , , , , , , ,							
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	No				
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)		NFPA Storage Level:					
e. Does the product contain DEHP?	No						
·							
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	Yes Group 1 items (antineoplastic)				
(if yes, answer a-e below and provide SDS)		If yes, indicate which:	Group Titeris (antineopiastic)				
a. UN/Identification Number							
	Proper Shipping Name		ardous Wasto Identification				
c. DOT Hazard Class		Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics				
		E. At liazardous Waste Code.	Waste Olidiacielistics				
Is this product regulated for shipment by IATA?	No	- DEMO	PECISTRY DESTRICTIONS				
(if yes, answer a-e below and provide SDS)		REMS o	or REGISTRY RESTRICTIONS				
a. UN/Identification Number		Is these a DEMO on this was due to	NI-				
b. Proper Shipping Name		Is there a REMS on this product?	No				
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?					
d. Packing Group	- NI-	Website URL:					
e. Inhalation Hazard?	No						
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	Yes				
Passenger		Limited Distribution Requirement	Yes				
Cargo		Comments / Details: (For example, iPledge program?)					
Passenger & Cargo							
Is this a reportable quantity? No		REMS:	No				
RQ Threshold:		REMS Program Manager Name:	Phone:				
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:	No				
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:	No				
No (if yes, identify method below)		Provider Name:	DEA #:				
Limited Quantity		Site Enrollment Number assigned	NCPDP#:				
Consumer Commodity, ORM-D		by Supplier:	NPI #:				
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP		Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#		Registry:					
ADDU OTODIO DE LOS CONTROLES DE LA CONTROLES D		Registry Program Contact Name:	Phone:				
ADD'L STORAGE INFORMATION		Comments					
Is the Product							
Controlled Substance? No Controlled Substance Code		R	RETURN INSTRUCTIONS				
Controlled by State(s)? No Listed Chemical (List I or II)	No						
ARCOS Reportable? No If yes, indicate which:		Contact tel. # if product received damaged:					
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:					
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	No						
Restricted to retail pharmacy only:	No	0					
		Special regulations or returns requirements for this product in certain states?	N. Committee of the com				
Restricted to hospital, clinics, and physician offices only:	No	'	No				
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?					
Comments:							
	MISCELLANE	OUS NOTES and/or Image of Product Barcode:					



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

#### Version 2024

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