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

Version 2020 | Introduction Type: Post Launch Change | X Final Version | Date: 6/6/2022

PRODUCT INFORMATION

Company Name:	Novadoz Pharmaceuticals, LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214366
DUNS:	08-110-9687
Proprietary Name (If Applicable) and Established Name:	Erlotinib Tablets 25mg, 30
Selling Unit NDC:	72205-080-30
Unit of Use NDC:	
UPC:	372205080300
UDI	
CVX Code:	
MVX Code:	
Description:	White coloured round shaped, biconvex, film coated tablets, Debossed with " E 25" on one side and plain on other side, free from physiscal defects.
Active Ingredient(s):	Erlotinib
URL for Additional Product Information:	
Address:	20 Duke Road
Address 2:	Suite A
City:	Piscataway
State:	NJ
Zip:	08854
Key Contact:	Seshu Akula
Email:	sesh.akula@novadozpharma.com
Phone Number:	908-887-0679
Fax:	732-902-2113
Product Therapeutic Classification:	Metastatic non-small cell lung cancer with epidermal growth factor receptor

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	Yes
correctional institution block?	No
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	Yes
If Unit Dose, indicate NDC here:	
Is the Product…	Direct-Ship Only
Is the Product…	Neither
Orphan Drug Status	
FDA Approval Status	
Allergens Present	No
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	30
Strength:	25mg
Dosage Form:	Tablets
Product Shape:	Round
Product Color:	White
Product Imprint:	E 25

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Tarceva

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
GLN:	
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
X	Item/Each	1		00372205080300	
	Box/Carton/Bundle/Inner Pack	12		20372205080304	
	Case	72		30372205080301	
	Pallet	2808		50372205080305	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No

b. Contact for temperature excursion questions:

Name:	P. Krishna Reddy
Number:	040-30449311
Group E-mail:	krishna_p@msnlabs.com

c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	Yes
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	Months

ORDER INFORMATION

Unit of Sale	
	Bottle
X	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sql
	Vial Power Multi
	Other: Write In

What is the NDC selling unit? 1 Carton of 1 bottle of 30 tablets (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

12	Each
	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 Carton (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	0.09	1.96	1.65	2.75	8.8935	1
Box/Carton/Bundle/ Inner Pack:	1.27	7.08	6.26	3.14	139.16731	12
Case:	8.615	13.77	8.66	11.02	1314.1152	72
Pallet:	375.694	47.24	39.37	37.79	70283.308	2808

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$210.00
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

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:

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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

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? No

Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? 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? No

Is this product regulated for shipment by 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? No

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#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard

☐ Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required No

Limited Distribution Requirement No

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

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: PCPDP#:

NPI #:

Comments

Registry: No

Registry Program Contact Name: Phone:

Comments

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No.

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 Yes

Restricted to retail pharmacy only: No

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

Restricted from US territories? (explain in comments) No

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

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:

Release DATE

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

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #: Name:

Phone:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Miscellaneous Notes:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:

Ships for second day receipt:

Ships regular ground for 3-10 days receipt:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method: Phone: Phone #:

Fax: Fax #:

EDI:

Overnight Fees apply:

Other fees apply:

Return Instructions

Contact # if product is received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?