

Erlotinib Tablets, 25 mg, 100 mg, and 150 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	<p><u>Erlotinib tablets are indicated for:</u></p> <ul style="list-style-type: none"> • The treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. • First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine. <p><u>Limitations of Use:</u></p> <ul style="list-style-type: none"> • Safety and efficacy of erlotinib tablets have not been established in patients with NSCLC whose tumours have other EGFR mutations. • Erlotinib tablet is not recommended for use in combination with platinum-based chemotherapy. <p><i>Please refer complete PI for more information</i></p>
2	Dosage	What is the recommended dosage?	<ul style="list-style-type: none"> • The recommended daily dose of erlotinib tablets for NSCLC is 150 mg. Treatment should continue until disease progression or unacceptable toxicity occurs. • The recommended daily dose of erlotinib tablets for pancreatic cancer is 100 mg taken once daily in combination with gemcitabine. Treatment should continue until disease progression or unacceptable toxicity occurs <p><i>Please refer complete PI for more information</i></p>
3	Administration	How do I take it?	Take erlotinib tablets on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food.
4	Formulation	Can tablet be crushed?	Swallow the tablet whole as prescribed by the physician. Do not split, crush or chew the tablet.
5	Administration	Use in Pediatric Population	The safety and effectiveness of erlotinib in pediatric patients have not been established.

6	Administration	Use in Geriatric Population	No overall differences in safety or efficacy were observed between subjects 65 years and older and those younger than 65.
7	Mechanism	Mechanism of Action	Epidermal growth factor receptor (EGFR) is expressed on the cell surface of both normal and cancer cells. In some tumor cells signaling through this receptor plays a role in tumor cell survival and proliferation irrespective of EGFR mutation status. Erlotinib reversibly inhibits the kinase activity of EGFR, preventing auto phosphorylation of tyrosine residues associated with the receptor and thereby inhibiting further downstream signaling. Erlotinib binding affinity for EGFR exon 19 deletion or exon 21 (L858R) mutations is higher than its affinity for the wild type receptor. Erlotinib inhibition of other tyrosine kinase receptors has not been fully characterized.
8	Warning	Black Box Warning	None.
9	Lactation	Use in Lactation	Lactating women were advised not to breastfeed during treatment with erlotinib and for 2 weeks after the final dose.
10	Pregnancy	Use in Pregnancy	Pregnant women should be advised of the potential risk to fetus. Advise females of reproductive potential to use effective contraception during therapy and for one month after the last dose of erlotinib.
11	Interaction	Is there any interaction with food?	Food increased the bioavailability of erlotinib to approximately 100%. Take erlotinib tablets on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food.
12	Side effects	What are the common side effects?	The most common side effects of Erlotinib tablets are rash, diarrhea, anorexia, fatigue, dyspnea, cough, nausea, and vomiting. <i>Please refer complete PI for more information</i>
13	Storage	What are the storage conditions?	Store at 25°C (77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F) in the original package. (See USP Controlled Room Temperature).
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15	Contraindication	What are the contraindications of (medication).	None.
Pharmaceutical Particulars			
16	Pharmaceutical Form	How is it supplied?	<ul style="list-style-type: none"> • 25 mg Tablets: White colored, round shaped, biconvex, film coated tablets, debossed with “E 25” on one side and plain on other side; supplied in: Bottles of 30: NDC 69539-090-30. • 100 mg Tablets: White colored, round shaped, biconvex, film coated, tablets, debossed with “E 100” on one side and plain on other side; supplied in: Bottles of 30: NDC 69539-091-30 150 mg Tablets: White colored, round shaped, biconvex, film coated tablets, debossed with “E 150” on one side and plain on other side; supplied in: Bottles of 30: NDC 69539-092-30.

17	Ingredients	Active and Inactive Ingredients	Active: Erlotinib hydrochloride Inactive: Hypromellose, Hydroxypropyl cellulose, Lactose monohydrate, Magnesium stearate, Microcrystalline cellulose, Propylene glycol, Sodium lauryl sulfate, Sodium starch glycolate, and Titanium dioxide.
18	Coating	What is the type of coating?	Film coated tablets
Allergens			
19	Ingredients	Is it Vegetarian?	No. Lactose is used as inactive ingredient which is produced from Milk source from healthy cows
20	Ingredients	Does it contain Gluten?	No
21	Ingredients	Does it contain Dairy Products?	Yes, Lactose is used as inactive ingredient which is produced from Milk source from healthy cows
22	Ingredients	Does it contain Casein?	No
23	Ingredients	Does it contain Whey?	No
24	Ingredients	Does it contain corn?	Yes, Starch used as inactive ingredient which is derived from maize starch/corn starch
25	Ingredients	Does it contain rye?	No
26	Ingredients	Does it contain sugar?	No
27	Ingredients	Does it contain Oats?	No
28	Ingredients	Does it contain wheat?	No
29	Ingredients	Does it contain spelt?	No
30	Ingredients	Does it contain barley?	No
31	Ingredients	Does it contain rennet?	No
32	Ingredients	Does it contain starch?	Yes, Starch used as inactive ingredient which is derived from maize starch/corn starch
33	Ingredients	Does it contain povidone?	No
34	Ingredients	Does it contain Iodine?	No
35	Ingredients	Does it contain latex?	No
36	Ingredients	Does it contain alcohol?	Yes, Erlotinib API Contains Methnol Not more than 3000 PPM and Isopropyl alcohol not more than 5000 PPM
37	Ingredients	Does it contain dyes?	No
38	Ingredients	Does it contain flavor?	No
39	Ingredients	Does it contain Lactose?	Yes, Lactose is used as inactive ingredient which is produced from Milk source from healthy cows
40	Ingredients	Does it contain Nuts?	No
41	Ingredients	Does it contain Preservatives?	No
42	Ingredients	Does it contain Soy	No

		products?	
43	Ingredients	Does it contain peanut?	No
44	Ingredients	Does it contain nickel?	No
Miscellaneous			
45	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products
46	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500.
47	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
48	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report SUSPECTED ADVERSE REACTIONS, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1- 800-FDA-1088 or www.fda.gov/medwatch.
49	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
50	Miscellaneous	Manufacturer and Distributor	<p>Manufactured by: MSN Laboratories Private Limited Telangana – 509 228, INDIA.</p> <p>Distributed by: Novadoz Pharmaceuticals Inc. Piscataway, NJ 08854-3714</p>