

ERLOTINIB- erlotinib tablet, film coated
Cadila Healthcare Limited

Erlotinib Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Erlotinib Tablets, 25 mg

30 tablets

NDC 70771-1521-3

Rx only



Erlotinib Tablets, 100 mg

30 tablets

NDC 70771-1522-3

Rx only



Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 70771-1522-3

Erlotinib Tablets

100 mg

30 Tablets
Rx only

Each film-coated tablet contains: 109.3 mg of erlotinib hydrochloride equivalent to 100 mg of erlotinib.

Usual Dosage: See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

This package is child-resistant.

Keep this and all drugs out of the reach of children.

Rev.: 04/20

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

zydus
pharmaceuticals

95 mm

41 mm

Erlotinib Tablets, 150 mg

30 tablets

NDC 70771-1523-3

Rx only



Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)



ERLOTINIB

erlotinib tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1521
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERLOTINIB HYDROCHLORIDE (UNII: DA87705X9K) (ERLOTINIB - UNII:J4T82NDH7E)	ERLOTINIB	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE (Off-white)	Score no score		
Shape	ROUND (Round)	Size 6mm		
Flavor		Imprint Code 913		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1521-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:70771-1521-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
3	NDC:70771-1521-7	3 in 1 CARTON	04/30/2020	
3	NDC:70771-1521-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA213065	04/30/2020		

ERLOTINIB			
erlotinib tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1522
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ERLOTINIB HYDROCHLORIDE (UNII: DA87705X9K) (ERLOTINIB - UNII:J4T82NDH7E)	ERLOTINIB	100 mg	
Inactive Ingredients			
Ingredient Name	Strength		
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)			
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)			
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)			
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)			

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (Off-white)	Score	no score
Shape	ROUND (Round)	Size	9mm
Flavor		Imprint Code	914
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1522-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:70771-1522-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
3	NDC:70771-1522-7	3 in 1 CARTON	04/30/2020	
3	NDC:70771-1522-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213065	04/30/2020	

ERLOTINIB

erlotinib tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1523
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERLOTINIB HYDROCHLORIDE (UNII: DA87705X9K) (ERLOTINIB - UNII:J4T82NDH7E)	ERLOTINIB	150 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
HYPROMELLOSE 2910 (6 MP.A.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	

POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (Off-white)	Score	no score
Shape	ROUND (Round)	Size	11mm
Flavor		Imprint Code	9 15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1523-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:70771-1523-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
3	NDC:70771-1523-7	3 in 1 CARTON	04/30/2020	
3	NDC:70771-1523-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213065	04/30/2020	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1521, 70771-1522, 70771-1523) , MANUFACTURE(70771-1521, 70771-1522, 70771-1523)