ERLOTINIB- erlotinib tablet, film coated
Cadila Healthcare Limited

Erlotinib Tablets

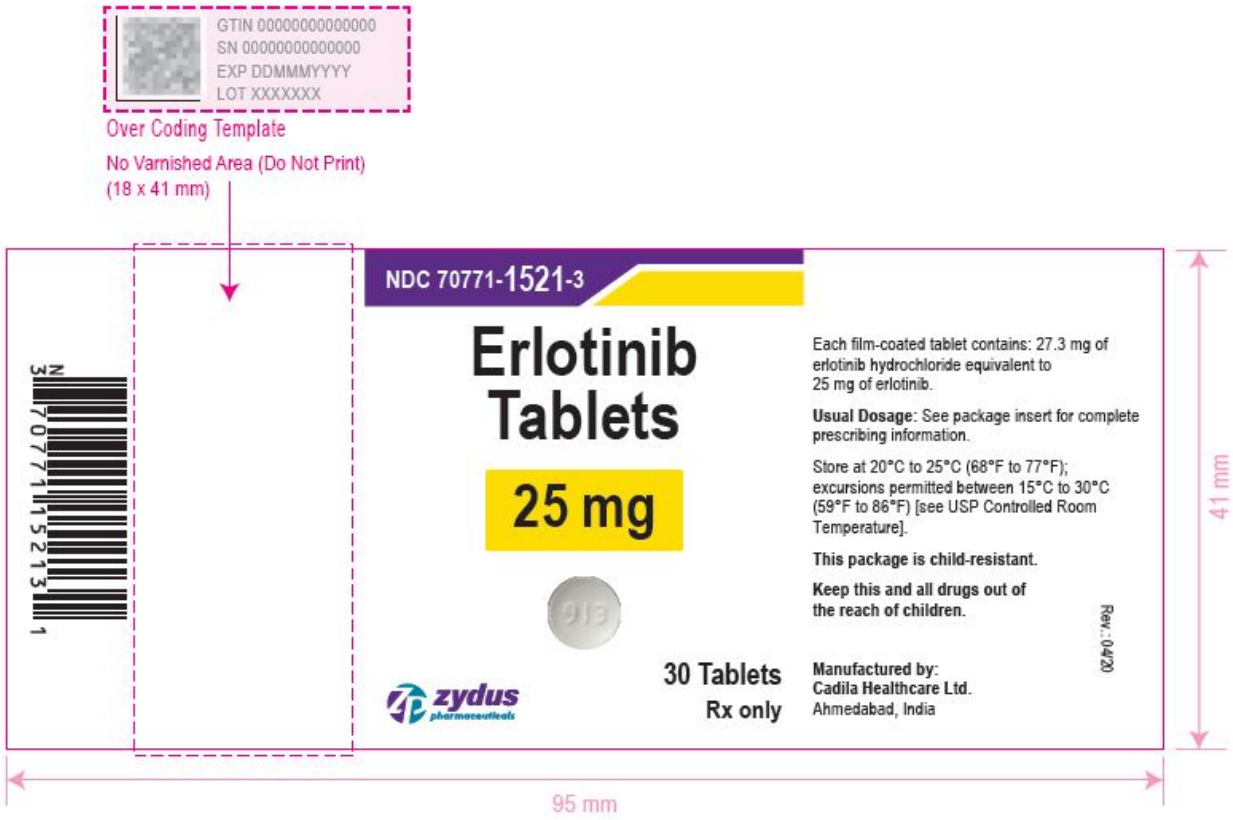
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Erlotinib Tablets, 25 mg

30 tablets

NDC 70771-1521-3

Rx only

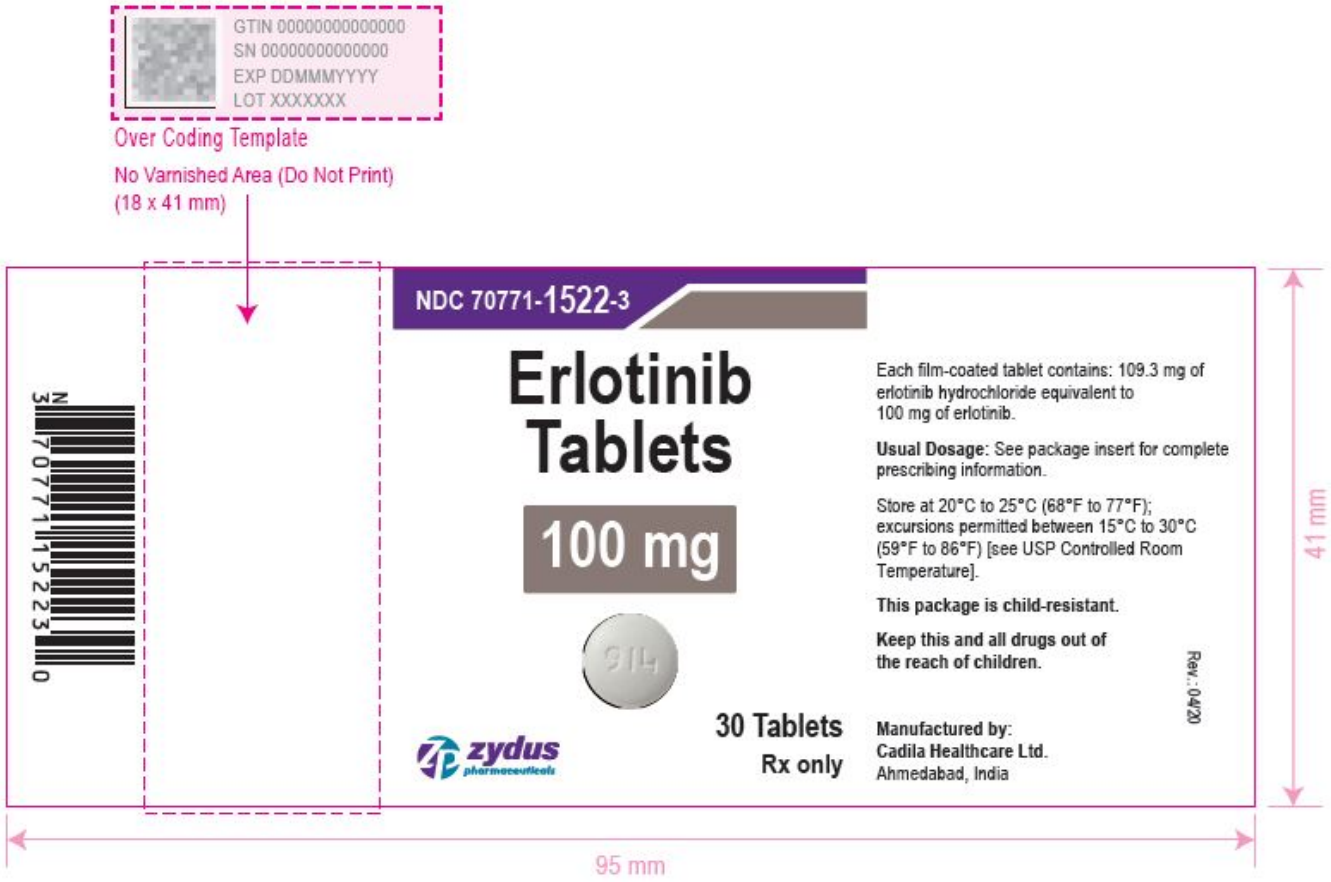


Erlotinib Tablets, 100 mg

30 tablets

NDC 70771-1522-3

Rx only

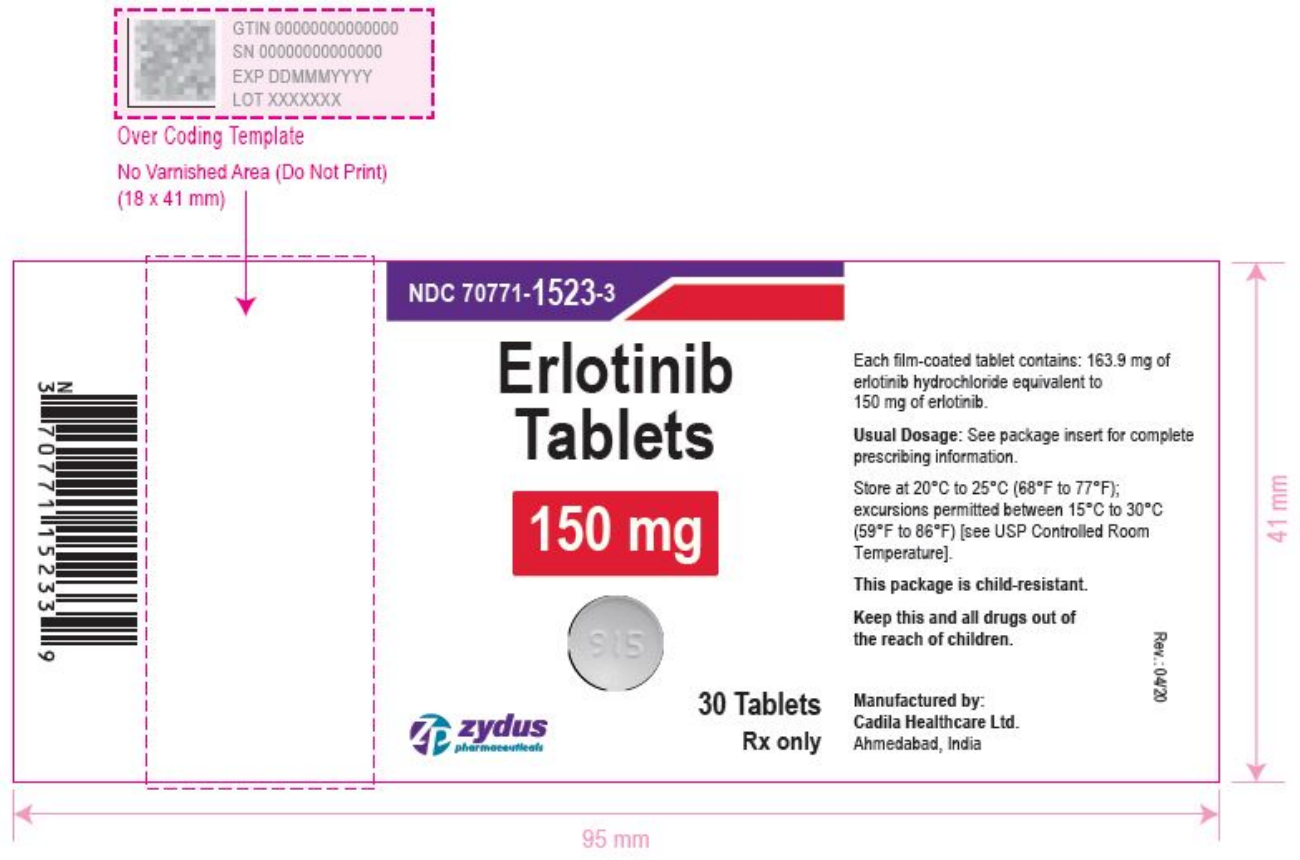


Erlotinib Tablets, 150 mg

30 tablets

NDC 70771-1523-3

Rx only



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**
CROSPOVIDONE (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: 4R4HFI6D95)	
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
CROSPOVIDONE (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: 4R4HFI6D95)	

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
CROSPOVIDONE (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: 4R4HFI6D95)	
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**	915
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)

Revised: 4/2020 Cadila Healthcare Limited