LANSOPRAZOLE- lansoprazole capsule, delayed release pellets
Zydus Lifesciences Limited

LANSOPRAZOLE DELAYED-RELEASE CAPSULES

Manufactured by:

Cadila Healthcare Ltd.

India.

SPL MEDGUIDE

NDC 65841-769-10 in bottle of 1000 Capsules

Lansoprazole Delayed-release Capsules USP, 15 mg

Rx only

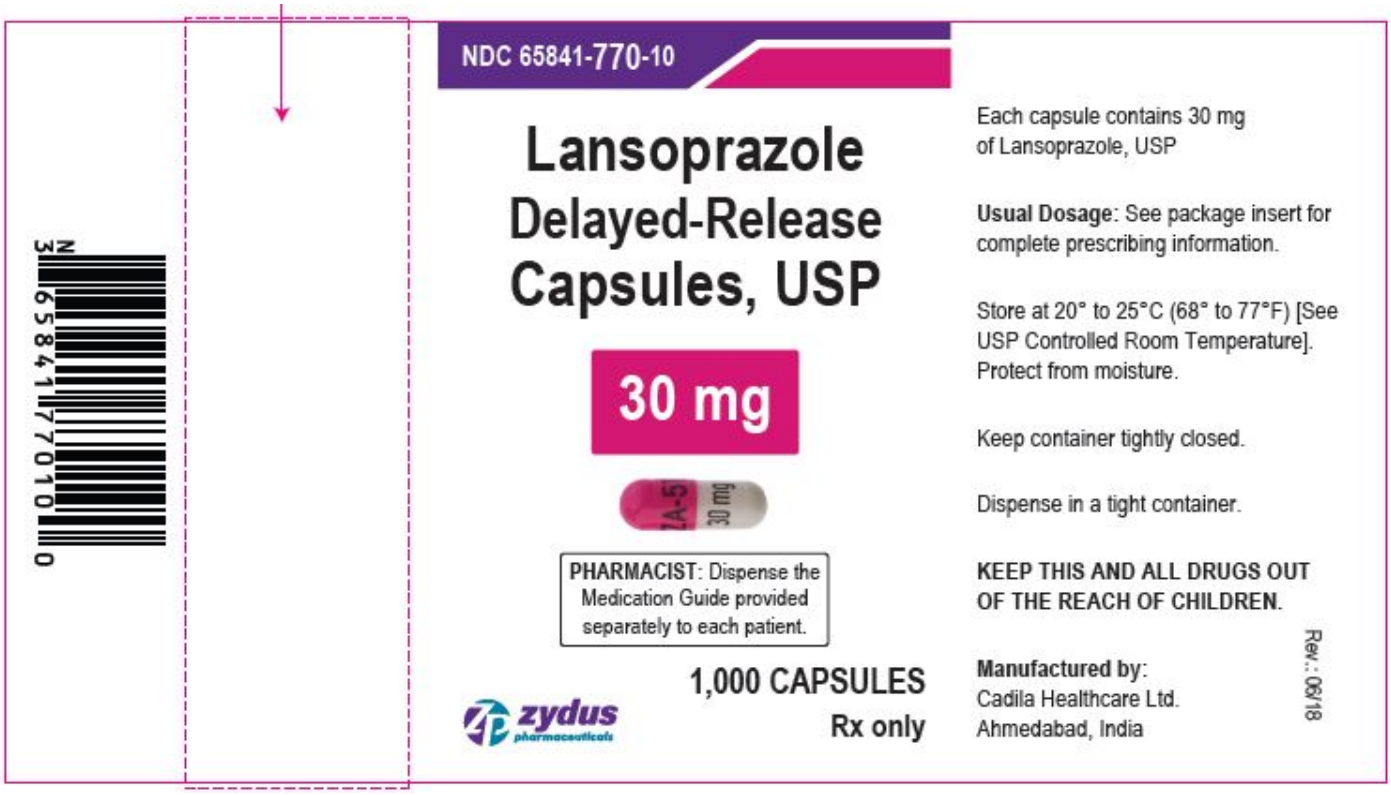
1000 Capsules

NDC 65841-770-10 in bottle of 1000 Capsules

Lansoprazole Delayed-release Capsules USP, 30 mg

Rx only

1000 Capsules



LANSOPRAZOLE

lansoprazole capsule, delayed release pellets

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-769
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LANSOPRAZOLE (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG)	LANSOPRAZOLE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SHELLAC (UNII: 46N107B71O)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PINK (PINK) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	16mm
Flavor		**Imprint Code**	ZA;50;15mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-769-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2013	
2	NDC:65841-769-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2013	
3	NDC:65841-769-30	10 in 1 CARTON	08/23/2013	
3		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	ANDA202366	08/23/2013	

LANSOPRAZOLE

lansoprazole capsule, delayed release pellets

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-770
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANSOPRAZOLE (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG)	LANSOPRAZOLE	30 mg

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SHELLAC (UNII: 46N107B71O)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PINK (PINK) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	20mm
Flavor		**Imprint Code**	ZA;51;30mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-770-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2013	
2	NDC:65841-770-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2013	
3	NDC:65841-	100 in 1 BOTTLE; Type 0: Not a Combination	08/23/2013	

3	770-01	Product	08/23/2013	
4	NDC:65841-770-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2013	
5	NDC:65841-770-30	10 in 1 CARTON	08/23/2013	
5		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	ANDA202366	08/23/2013	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-769, 65841-770) , MANUFACTURE(65841-769, 65841-770)

Revised: 9/2023 Zydus Lifesciences Limited