

LANSOPRAZOLE- lansoprazole tablet, orally disintegrating
Zydus Lifesciences Limited

LANSOPRAZOLE DELAYED-RELEASE ORALLY DISINTEGRATING TABLETS

SPL MEDGUIDE

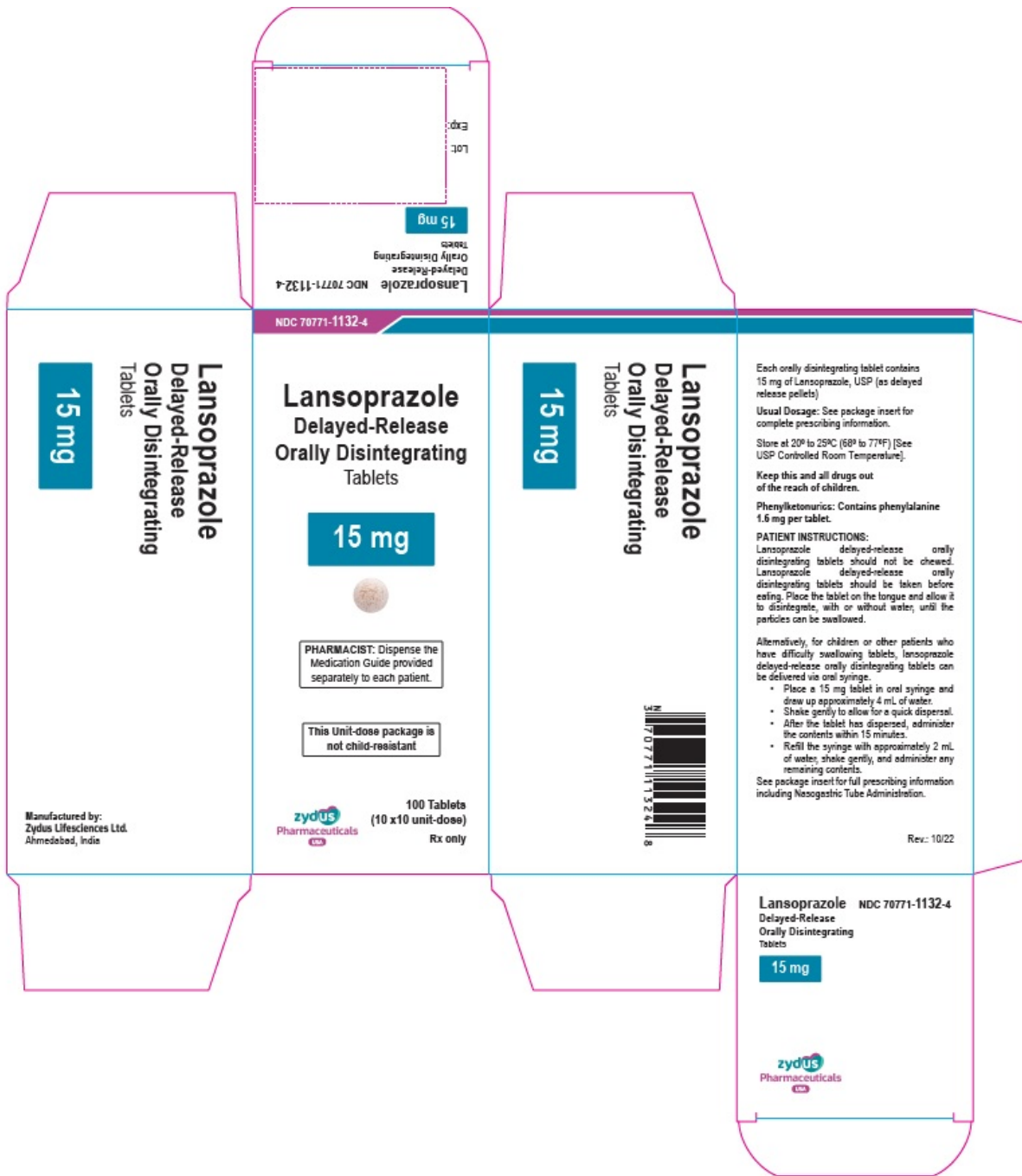
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1132-4

Lansoprazole Delayed-release Orally Disintegrating Tablets, 15 mg

R_x only

100 Tablets (10 x 10 Unit Dose)



NDC 70771-1133-4

Lansoprazole Delayed-release Orally Disintegrating Tablets, 30 mg

R_x only

100 Tablets (10 x 10 Unit Dose)



LANSOPRAZOLE

lansoprazole tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1132
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor	STRAWBERRY (STRAWBERRY)	Imprint Code	771
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1132-4	10 in 1 CARTON	11/30/2018	
1		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	ANDA200816	11/30/2018	

LANSOPRAZOLE

lansoprazole tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1133
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	13mm
Flavor	STRAWBERRY (STRAWBERRY)	Imprint Code	772
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1133-4	10 in 1 CARTON	11/30/2018	
1		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	ANDA200816	11/30/2018	

Labeler - Zydus Lifesciences Limited (918596198)**Registrant** - Zydus Lifesciences Limited (918596198)**Establishment**

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1132, 70771-1133) , MANUFACTURE(70771-1132, 70771-1133)

Revised: 9/2023

Zydus Lifesciences Limited