NADOLOL- nadolol tablet
Zydus Lifesciences Limited

Nadolol Tablets, USP

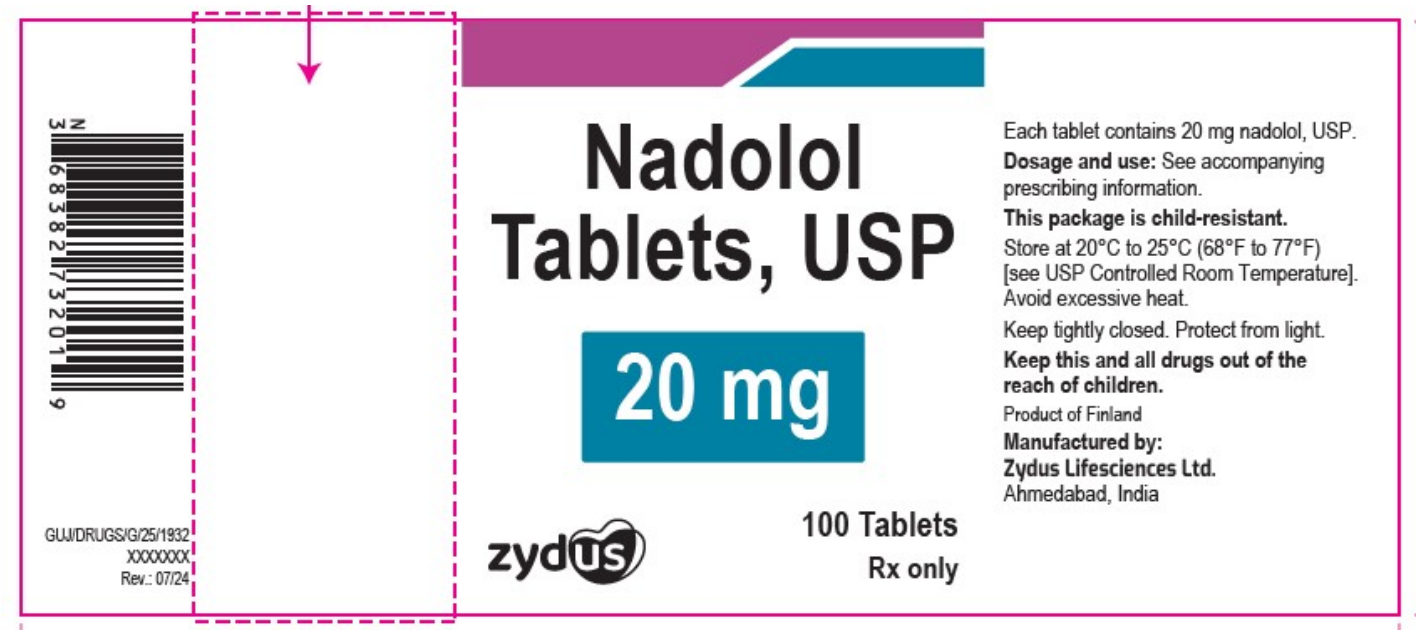
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1089-1

Nadolol tablets, 20 mg

Rx only

100 tablets

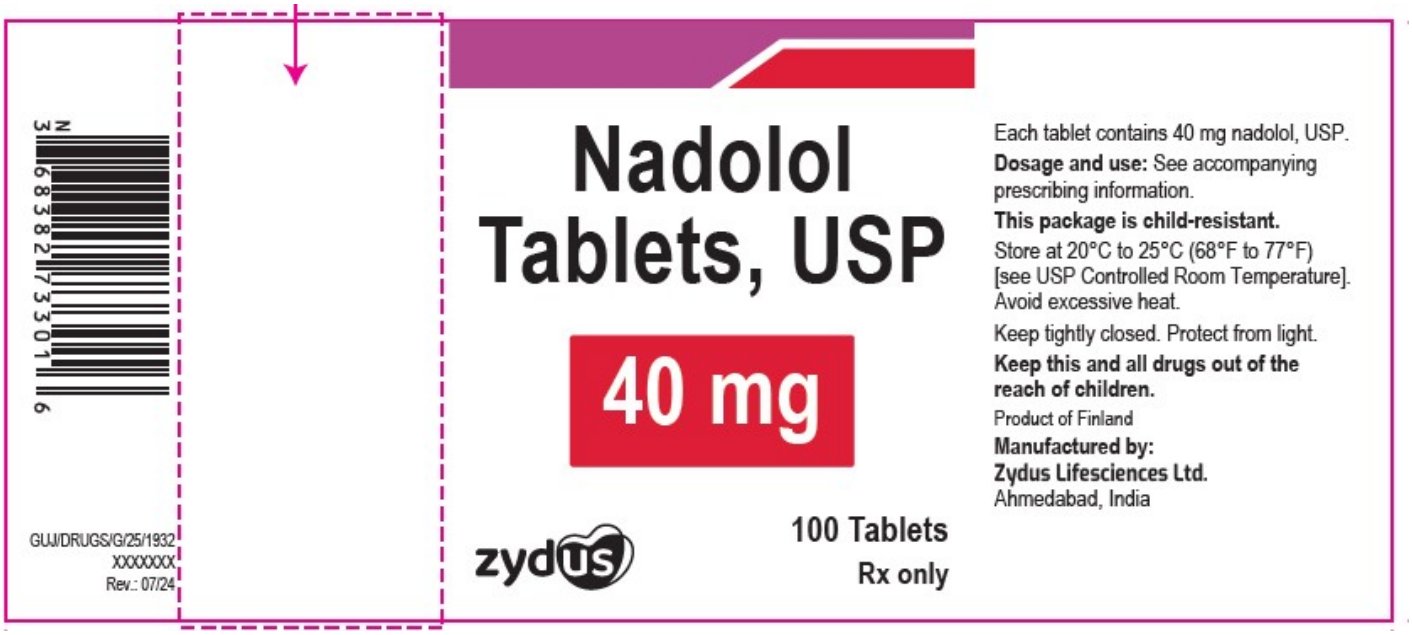


NDC 70771-1090-1

Nadolol tablets, 40 mg

Rx only

100 tablets

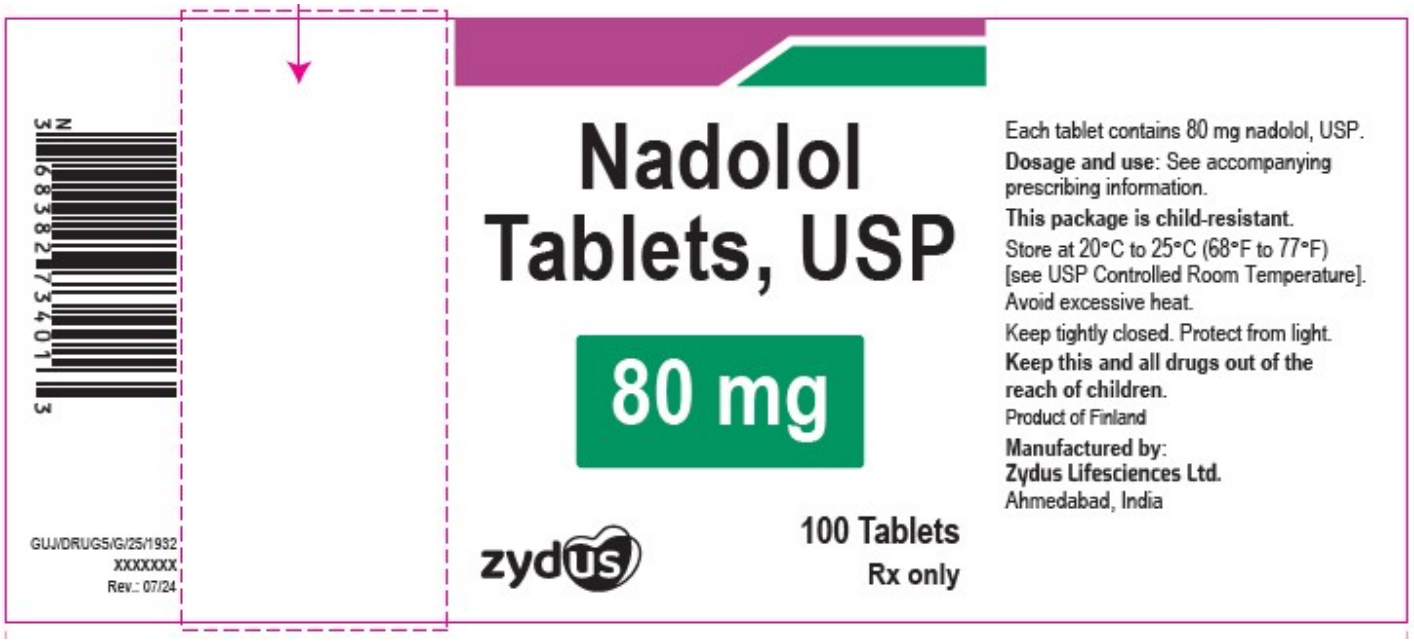


NDC 70771-1091-1

Nadolol tablets, 80 mg

Rx only

100 tablets



NADOLOL nadolol tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1090

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NADOLOL (UNII: FEN504330V) (NADOLOL - UNII:FEN504330V)	NADOLOL	40 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	N;40
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1090-4	10 in 1 CARTON	08/08/2017	
1	NDC:70771-1090-2	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1090-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	
3	NDC:70771-1090-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	
4	NDC:70771-1090-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207761	08/08/2017	

NADOLOL

nadolol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1091
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NADOLOL (UNII: FEN504330V) (NADOLOL - UNII:FEN504330V)	NADOLOL	80 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BLUE (BLUE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	11mm
Flavor		**Imprint Code**	N;80
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1091-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	
2	NDC:70771-1091-4	10 in 1 CARTON	08/08/2017	
2	NDC:70771-1091-2	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:70771-1091-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	
4	NDC:70771-1091-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA207761	08/08/2017	

NADOLOL

nadolol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1089
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NADOLOL (UNII: FEN504330V) (NADOLOL - UNII:FEN504330V)	NADOLOL	20 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (OFF-WHITE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	N;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1089-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	
2	NDC:70771-1089-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	
3	NDC:70771-1089-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2017	
4	NDC:70771-1089-4	10 in 1 CARTON	08/08/2017	
4	NDC:70771-1089-2	1 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	ANDA207761	08/08/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1089, 70771-1090, 70771-1091) , MANUFACTURE(70771-1089, 70771-1090, 70771-1091)

Revised: 12/2024 Zydus Lifesciences Limited