ATENOLOL - atenolol tablet
Zydus Lifesciences Limited

Atenolol Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-022-01 in bottles of 100 tablets

Atenolol Tablets USP, 25 mg

R_x only

100 Tablets

NDC 65841-023-01 in bottles of 100 tablets

Atenolol Tablets USP, 50 mg

R_x only

100 Tablets

NDC 65841-024-01 in bottles of 100 tablets

Atenolol Tablets USP, 100 mg

R_x only

100 Tablets

ATENOLOL

atenolol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-022
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATENOLOL (UNII: 50VV3VW0TI) (ATENOLOL - UNII:50VV3VW0TI)	ATENOLOL	25 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	Z;65
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-022-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
2	NDC:65841-022-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
3	NDC:65841-022-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
4	NDC:65841-022-40	5000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
5	NDC:65841-022-24	10000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076900	10/08/2005	

ATENOLOL

atenolol tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-023
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATENOLOL (UNII: 50VV3VW0TI) (ATENOLOL - UNII:50VV3VW0TI)	ATENOLOL	50 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	Z;66
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-023-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
2	NDC:65841-023-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
3	NDC:65841-023-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
4	NDC:65841-023-02	2000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
5	NDC:65841-023-40	5000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
6	NDC:65841-023-24	10000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076900	10/08/2005	

ATENOLOL

atenolol tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-024
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ATENOLOL (UNII: 50VV3VW0TI) (ATENOLOL - UNII:50VV3VW0TI)	ATENOLOL	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE (WHITE TO OFF- WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	Z;67
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-024-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
2	NDC:65841-024-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
3	NDC:65841-024-40	5000 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	
4	NDC:65841-024-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076900	10/08/2005	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-022, 65841-023, 65841-024) , MANUFACTURE(65841-022, 65841-023, 65841-024)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(65841-022, 65841-023, 65841-024) , MANUFACTURE(65841-022, 65841-023, 65841-024)

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