CARVEDILOL - carvedilol tablet, film coated
Zydus Lifesciences Limited

CARVEDILOL TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-616-01 in bottle of 100 Tablets

Carvedilol Tablets USP, 3.125 mg

R_x only

100 Tablets

NDC 65841-617-01 in bottle of 100 Tablets

Carvedilol Tablets USP, 6.25 mg

R_x only

100 Tablets

NDC 65841-618-01 in bottle of 100 Tablets

Carvedilol Tablets USP, 12.5 mg

R_x only

100 Tablets

NDC 65841-619-01 in bottle of 100 Tablets

Carvedilol Tablets USP, 25 mg

R_x only

100 Tablets

CARVEDILOL

carvedilol tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-616
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARVEDILOL (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	3.125 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSPOVIDONE (12 MPA.S AT 5%) (UNII: 40UAA97IT9)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score

Shape	ROUND (ROUND)	**Size**	4mm
Flavor		**Imprint Code**	Z;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-616-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-616-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-616-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

CARVEDILOL

carvedilol tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-617
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARVEDILOL (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (12 MPA.S AT 5%) (UNII: 40UAA97IT9)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	ZC40
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-617-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-617-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-617-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

CARVEDILOL

carvedilol tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-618
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARVEDILOL (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (12 MPA.S AT 5%) (UNII: 40UAA97IT9)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	ZC41
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-618-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-618-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-618-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

CARVEDILOL

carvedilol tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-619
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARVEDILOL (UNII: 0K47UL67F2) (CARVEDILOL - UNII:0K47UL67F2)	CARVEDILOL	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (12 MPA.S AT 5%) (UNII: 40UAA97IT9)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	ZC42
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-619-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
2	NDC:65841-619-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	
3	NDC:65841-619-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077614	09/05/2007	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-616, 65841-617, 65841-618, 65841-619) , MANUFACTURE(65841-616, 65841-617, 65841-618, 65841-619)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(65841-616, 65841-617, 65841-618, 65841-619) , MANUFACTURE(65841-616, 65841-617, 65841-618, 65841-619)