PRAVASTATIN SODIUM - pravastatin sodium tablet
Zydus Lifesciences Limited

PRAVASTATIN SODIUM TABLETS

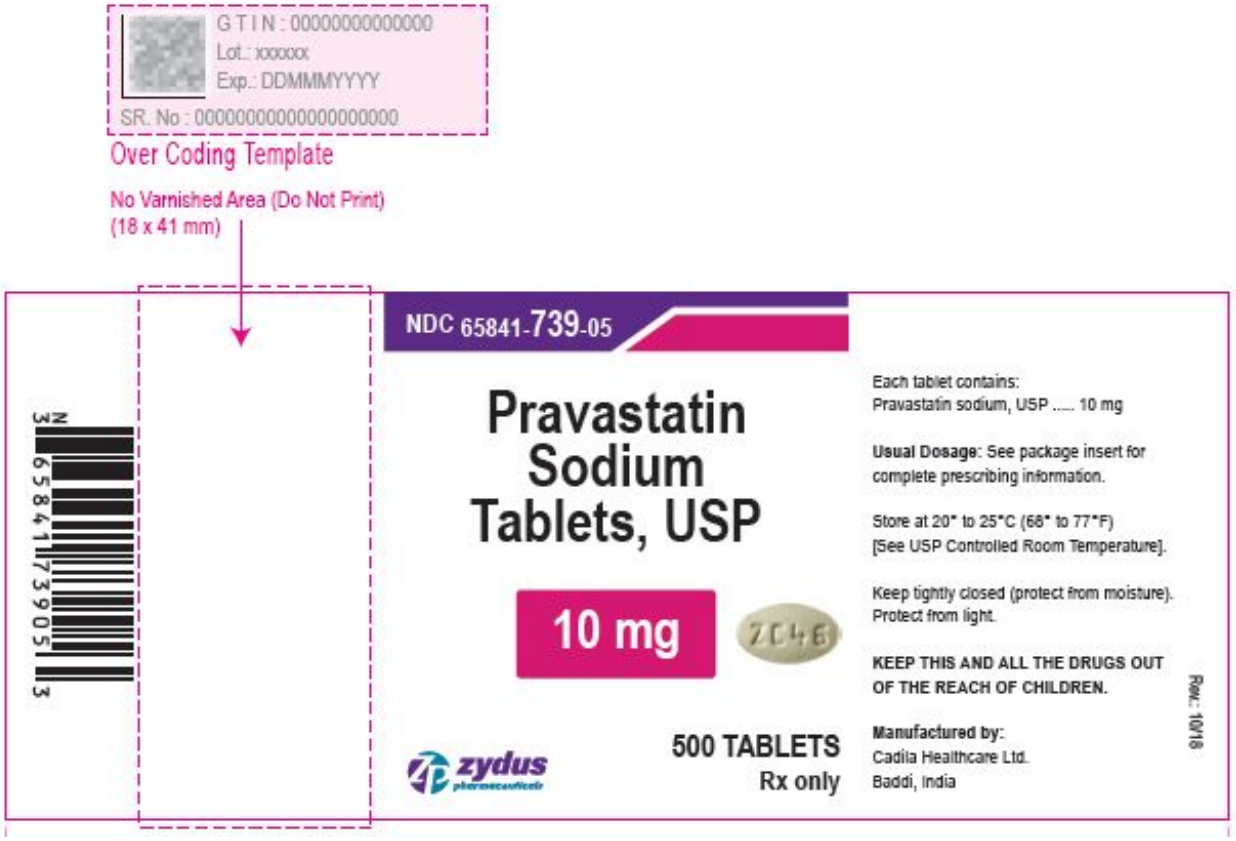
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-739-05 in bottle of 500 tablets

Pravastatin Sodium Tablets USP, 10 mg

R_x only

500 tablets

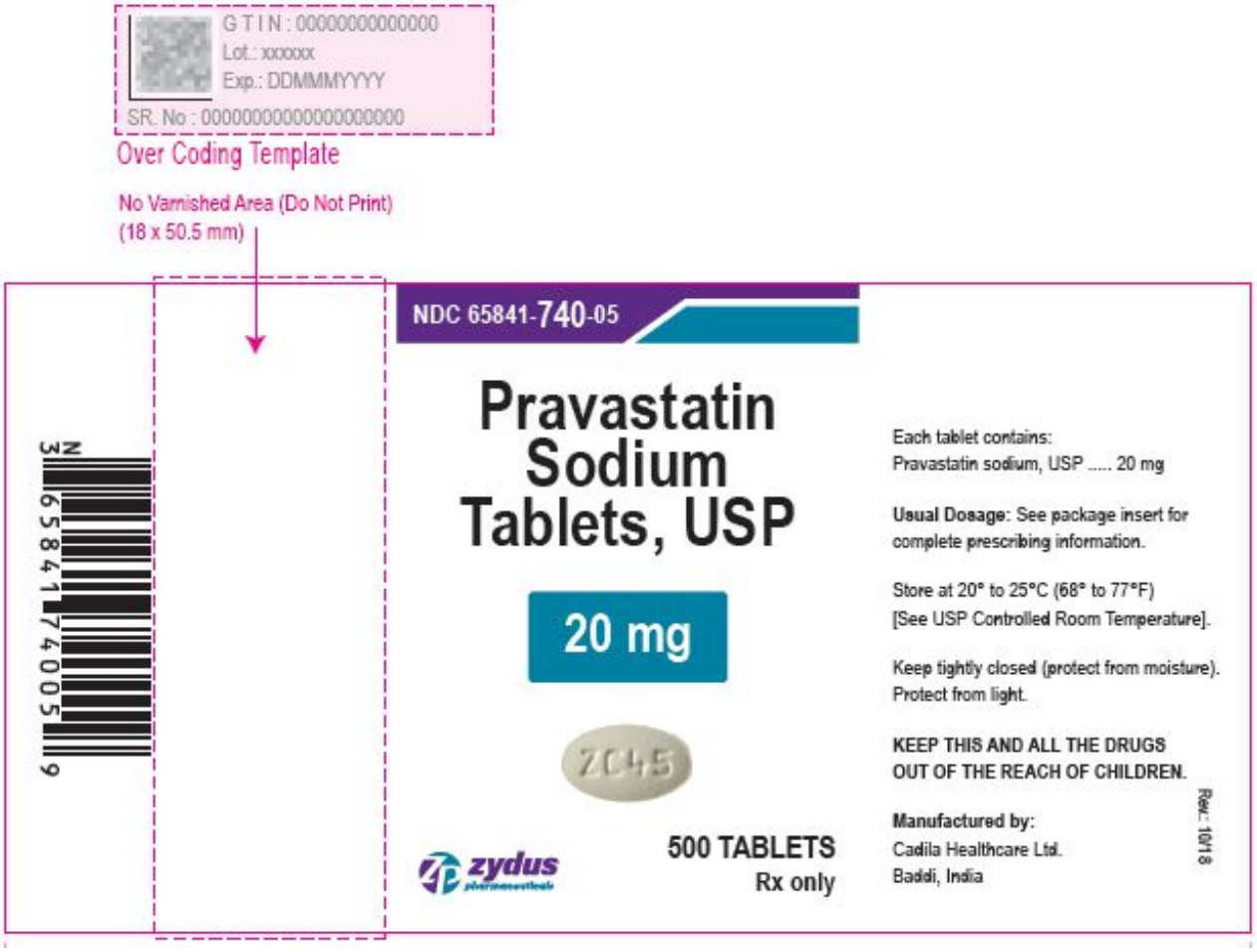


NDC 65841-740-05 in bottle of 500 tablets

Pravastatin Sodium Tablets USP, 20 mg

R_x only

500 tablets

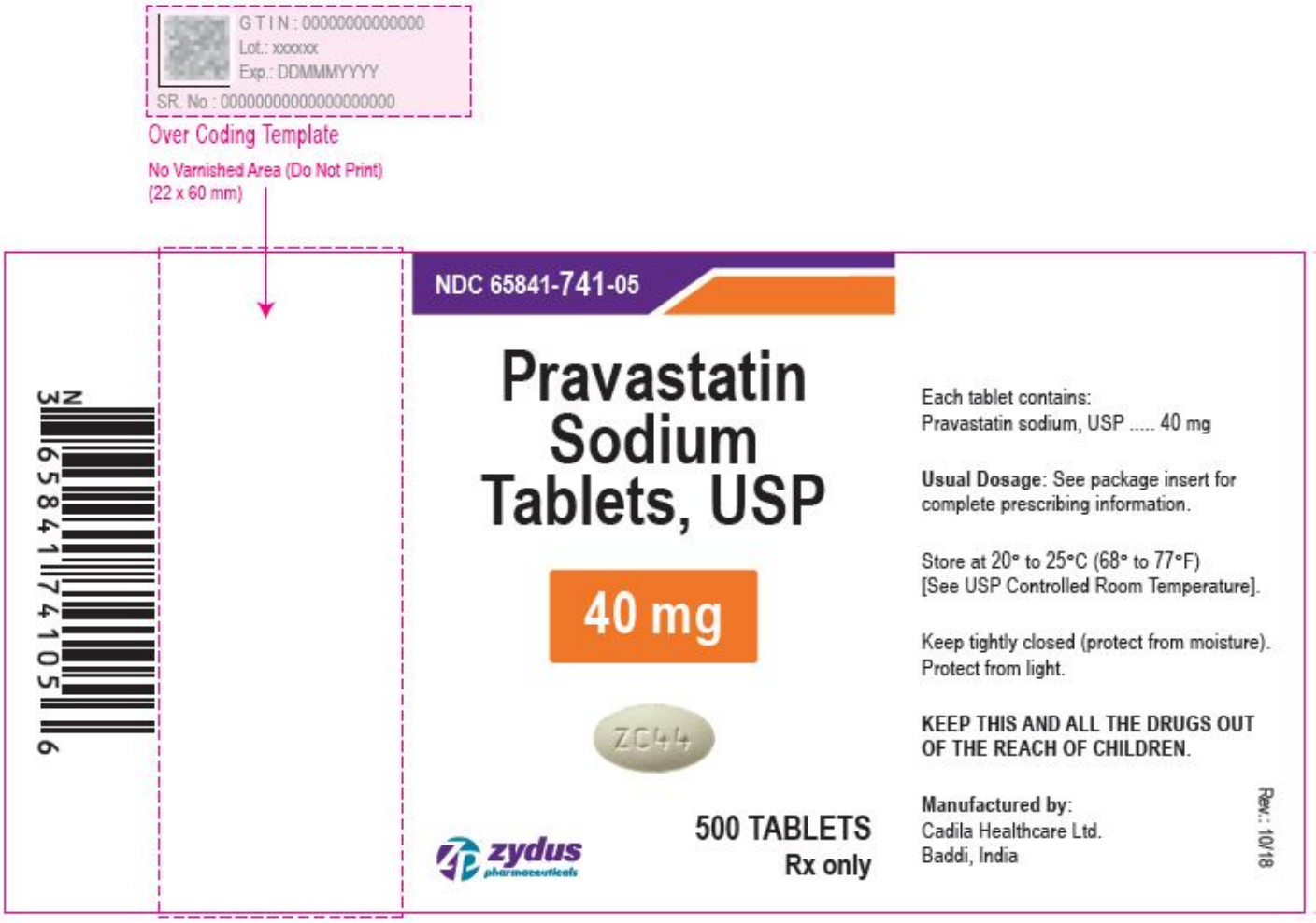


NDC 65841-741-05 in bottle of 500 tablets

Pravastatin Sodium Tablets USP, 40 mg

R_x only

500 tablets



NDC 65841-742-05 in bottle of 500 tablets

Pravastatin Sodium Tablets USP, 80 mg

R_x only

500 tablets

PRAVASTATIN SODIUM

pravastatin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-739
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAVASTATIN SODIUM (UNII: 3M8608UQ61) (PRAVASTATIN - UNII:KXO2KT9N0G)	PRAVASTATIN SODIUM	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	9mm
Flavor		**Imprint Code**	ZC46
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-739-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	
2	NDC:65841-739-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077751	03/30/2010	

PRAVASTATIN SODIUM

pravastatin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-740
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAVASTATIN SODIUM (UNII: 3M8608UQ61) (PRAVASTATIN - UNII:KXO2KT9N0G)	PRAVASTATIN SODIUM	20 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	ZC45
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-740-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	
2	NDC:65841-740-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	
3	NDC:65841-740-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077751	03/30/2010	

PRAVASTATIN SODIUM

pravastatin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-741
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PRAVASTATIN SODIUM (UNII: 3M8608UQ61) (PRAVASTATIN - UNII:KXO2KT9N0G)	PRAVASTATIN SODIUM	40 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	14mm
Flavor		**Imprint Code**	ZC44
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-741-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	
2	NDC:65841-741-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077751	03/30/2010	

PRAVASTATIN SODIUM

pravastatin sodium tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-742
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAVASTATIN SODIUM (UNII: 3M8608UQ61) (PRAVASTATIN - UNII:KXO2KT9N0G)	PRAVASTATIN SODIUM	80 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

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

Shape	OVAL (OVAL)	**Size**	19mm
Flavor		**Imprint Code**	ZC43
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-742-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	
2	NDC:65841-742-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077751	03/30/2010	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(65841-739, 65841-740, 65841-741, 65841-742) , MANUFACTURE(65841-739, 65841-740, 65841-741, 65841-742)

Revised: 10/2022 Zydus Lifesciences Limited