

PRAVASTATIN SODIUM- pravastatin sodium tablet
Cadila Healthcare Limited

PRAVASTATIN SODIUM TABLETS

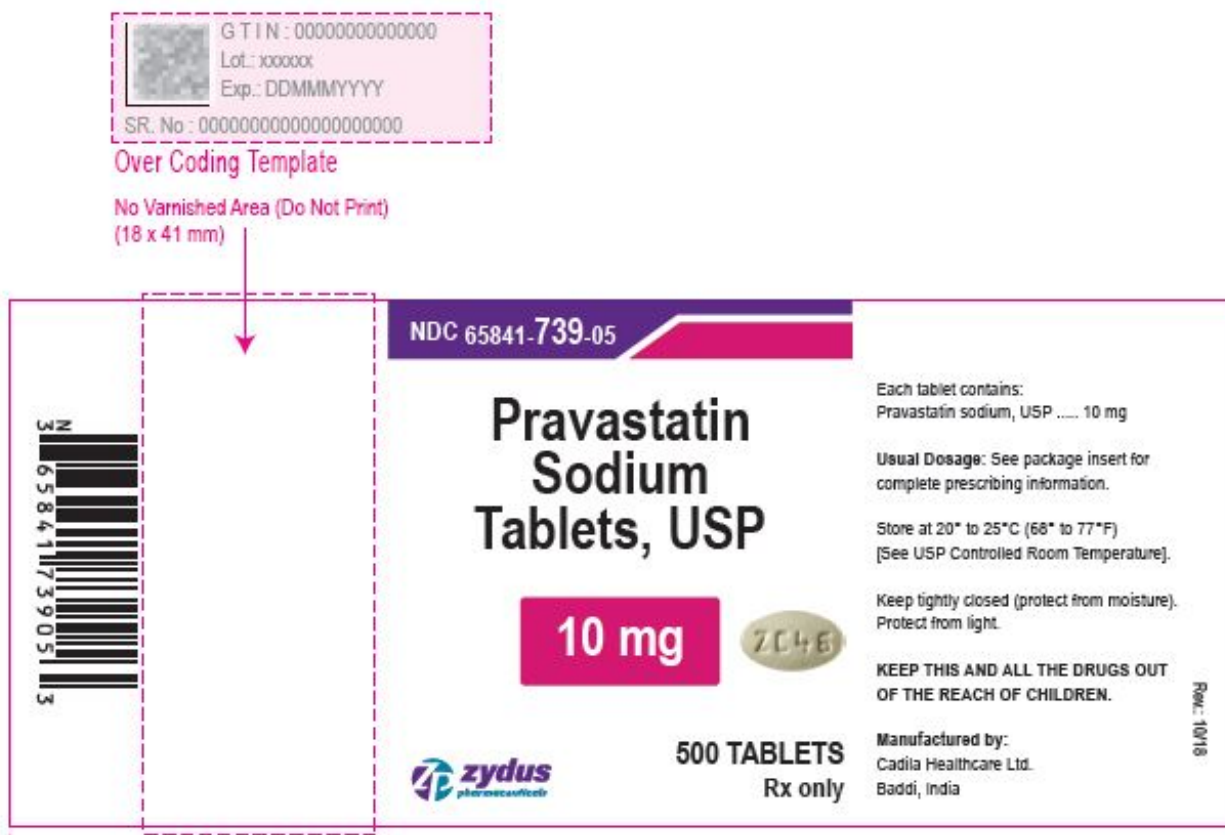
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

GTIN : 00000000000000
Lot : xxxxxx
Exp : DDMMYYYY
SR. No : 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
(18 x 50.5 mm)

NDC 65841-740-05

Pravastatin Sodium Tablets, USP

20 mg

500 TABLETS
Rx only

zydus
pharmaceuticals

Each tablet contains:
Pravastatin sodium, USP 20 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

Keep tightly closed (protect from moisture).
Protect from light.

**KEEP THIS AND ALL THE DRUGS
OUT OF THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Baddi, India

Rev: 10/18

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6584174005
9

NDC 65841-741-05 in bottle of 500 tablets

Pravastatin Sodium Tablets USP, 40 mg

R_x only

500 tablets

GTIN : 00000000000000
Lot : xxxxxx
Exp : DDMMYYYY
SR. No : 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
(22 x 60 mm)

NDC 65841-741-05

Pravastatin Sodium Tablets, USP

40 mg

500 TABLETS
Rx only

zydus
pharmaceuticals

Each tablet contains:
Pravastatin sodium, USP 40 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

Keep tightly closed (protect from moisture).
Protect from light.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Baddi, India

Rev.: 10/18

NDC 65841-742-05 in bottle of 500 tablets

Pravastatin Sodium Tablets USP, 80 mg

R_x only

500 tablets

GTIN : 00000000000000
 Lot : xxxxxx
 Exp. : DDMMYYYY
 SR. No : 0000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
 (26 x 75 mm)



NDC 65841-742-05

Pravastatin Sodium Tablets, USP

80 mg



500 TABLETS
Rx only



Each tablet contains:
Pravastatin sodium, USP 80 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

Keep tightly closed (protect from moisture).
Protect from light.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Baddi, India

Rev: 10/18

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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYOXYL 35 CASTOR OIL (UNII: 6D4MIDAL6O)	
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
CROSCARMELOSE 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
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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: 3S5Y5LH9PMK)	

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 - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
CADILA HEALTHCARE LIMITED		677605858	ANALYSIS(65841-739, 65841-740, 65841-741, 65841-742) , MANUFACTURE(65841-739, 65841-740, 65841-741, 65841-742)

Revised: 9/2020

Cadila Healthcare Limited