SIMVASTATIN - simvastatin tablet, film coated
Zydus Lifesciences Limited

SIMVASTATIN TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-065-16 in bottle of 90 tablets

Simvastatin Tablets USP, 5 mg

Rx only

NDC 65841-066-16 in bottle of 90 tablets

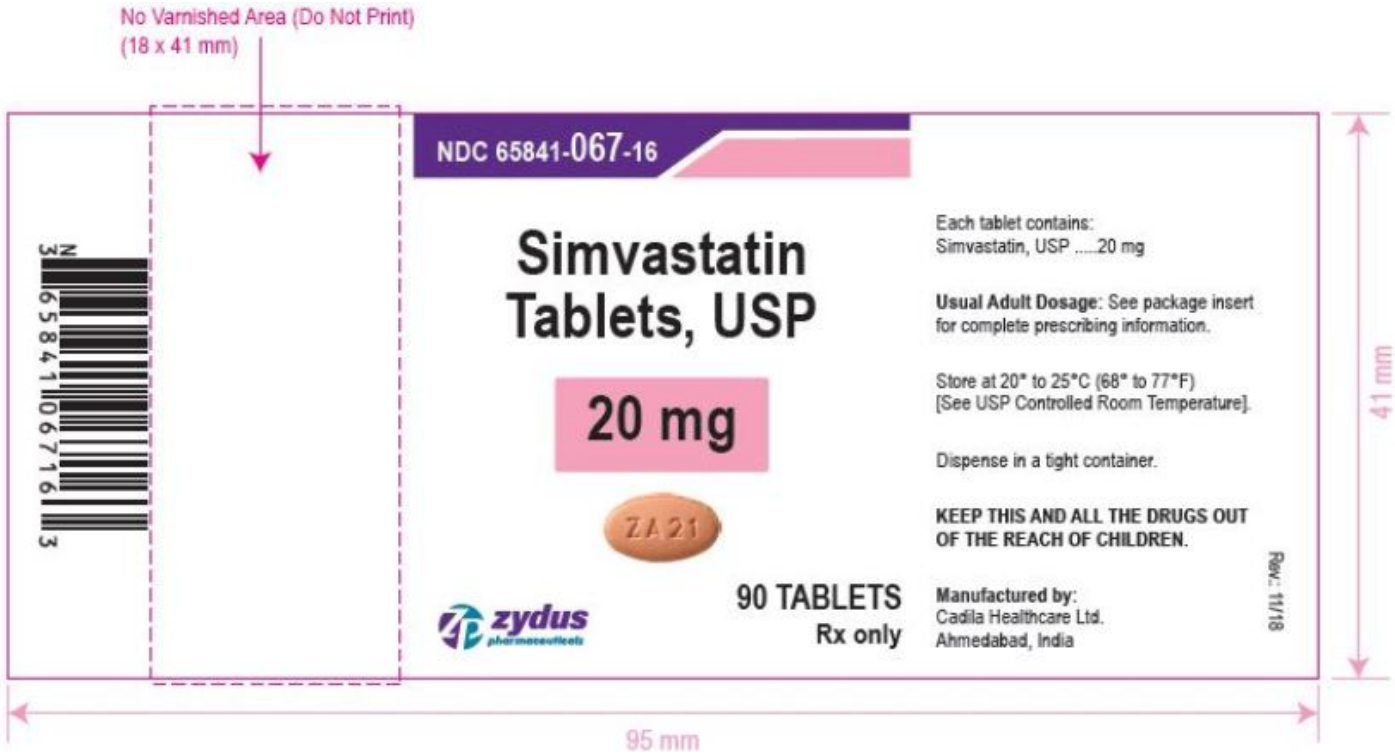
Simvastatin Tablets USP, 10 mg

Rx only

NDC 65841-067-16 in bottle of 90 tablets

Simvastatin Tablets USP, 20 mg

Rx only



NDC 65841-068-16 in bottle of 90 tablets

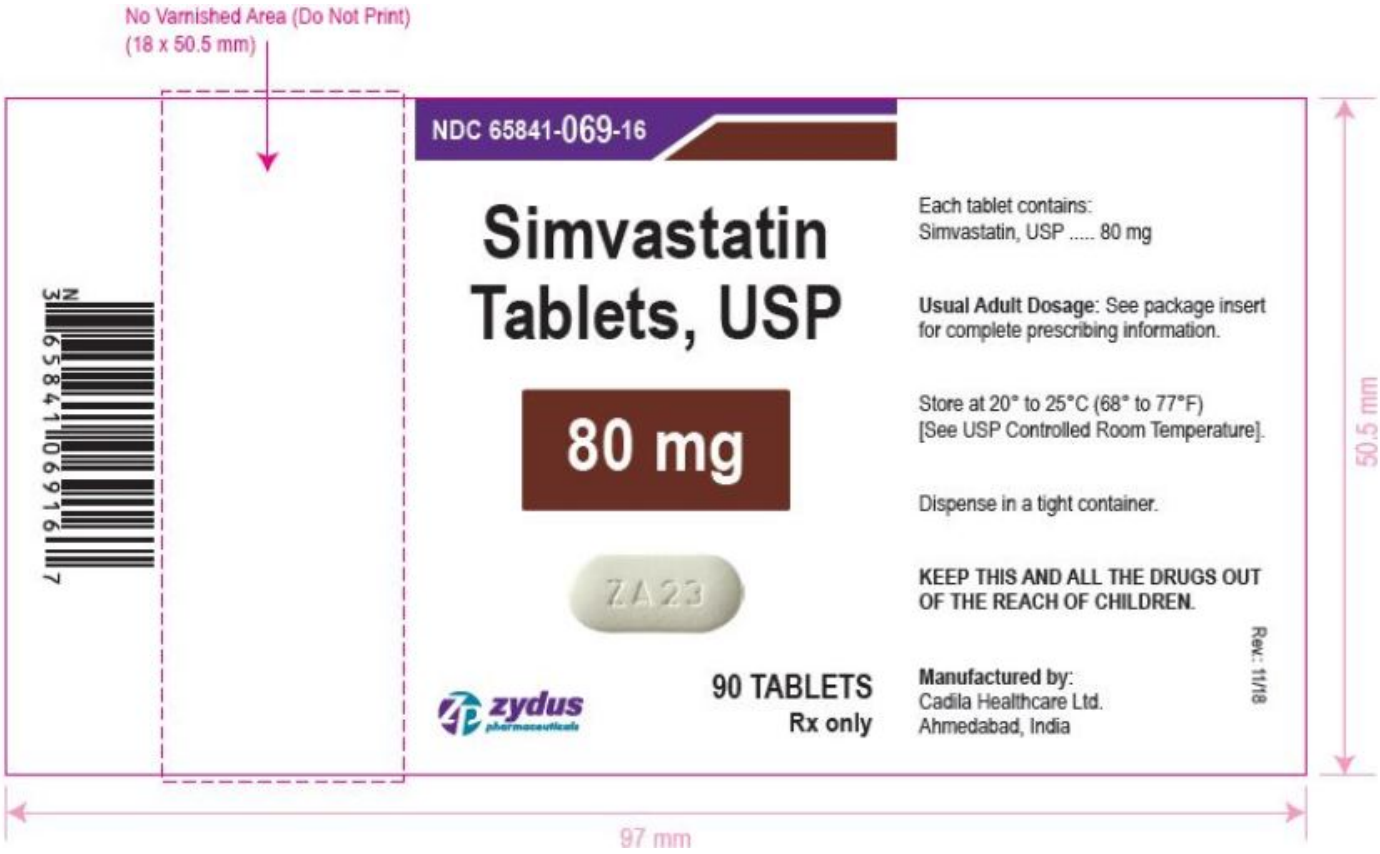
Simvastatin Tablets USP, 40 mg

Rx only

NDC 65841-069-16 in bottle of 90 tablets

Simvastatin Tablets USP, 80 mg

Rx only



SIMVASTATIN

simvastatin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-065
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SIMVASTATIN (UNII: AGG2FN16EV) (SIMVASTATIN - UNII:AGG2FN16EV)	SIMVASTATIN	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (WHITE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	9mm
Flavor		**Imprint Code**	ZA19
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-065-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
2	NDC:65841-065-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
3	NDC:65841-065-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
4	NDC:65841-065-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
5	NDC:65841-065-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077837	12/20/2006	

SIMVASTATIN

simvastatin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-066
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SIMVASTATIN (UNII: AGG2FN16EV) (SIMVASTATIN - UNII:AGG2FN16EV)	SIMVASTATIN	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	9mm
Flavor		**Imprint Code**	ZA20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-066-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
2	NDC:65841-066-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
3	NDC:65841-066-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
4	NDC:65841-066-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
5	NDC:65841-066-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
6	NDC:65841-066-24	10000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077837	12/20/2006	

SIMVASTATIN

simvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-067
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

SIMVASTATIN (UNII: AGG2FN16EV) (SIMVASTATIN - UNII:AGG2FN16EV)	SIMVASTATIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (BROWN)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	ZA21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-067-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
2	NDC:65841-067-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
3	NDC:65841-067-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
4	NDC:65841-067-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
5	NDC:65841-067-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
6	NDC:65841-067-24	10000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077837	12/20/2006	

SIMVASTATIN

simvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-068
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SIMVASTATIN (UNII: AGG2FN16EV) (SIMVASTATIN - UNII:AGG2FN16EV)	SIMVASTATIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	14mm
Flavor		**Imprint Code**	ZA22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-068-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
2	NDC:65841-068-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
3	NDC:65841-068-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
4	NDC:65841-068-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
5	NDC:65841-068-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
6	NDC:65841-068-40	5000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077837	12/20/2006	

SIMVASTATIN

simvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-069
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SIMVASTATIN (UNII: AGG2FN16EV) (SIMVASTATIN - UNII:AGG2FN16EV)	SIMVASTATIN	80 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	ZA23
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-069-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
2	NDC:65841-069-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
3	NDC:65841-069-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	

4	NDC:65841-069-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
5	NDC:65841-069-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077837	12/20/2006	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-065, 65841-066, 65841-067, 65841-068, 65841-069) , MANUFACTURE(65841-065, 65841-066, 65841-067, 65841-068, 65841-069)

Revised: 10/2022 Zydus Lifesciences Limited