ROSUVASTATIN - rosuvastatin tablet, film coated
Zydus Lifesciences Limited

ROSUVASTATIN TABLETS

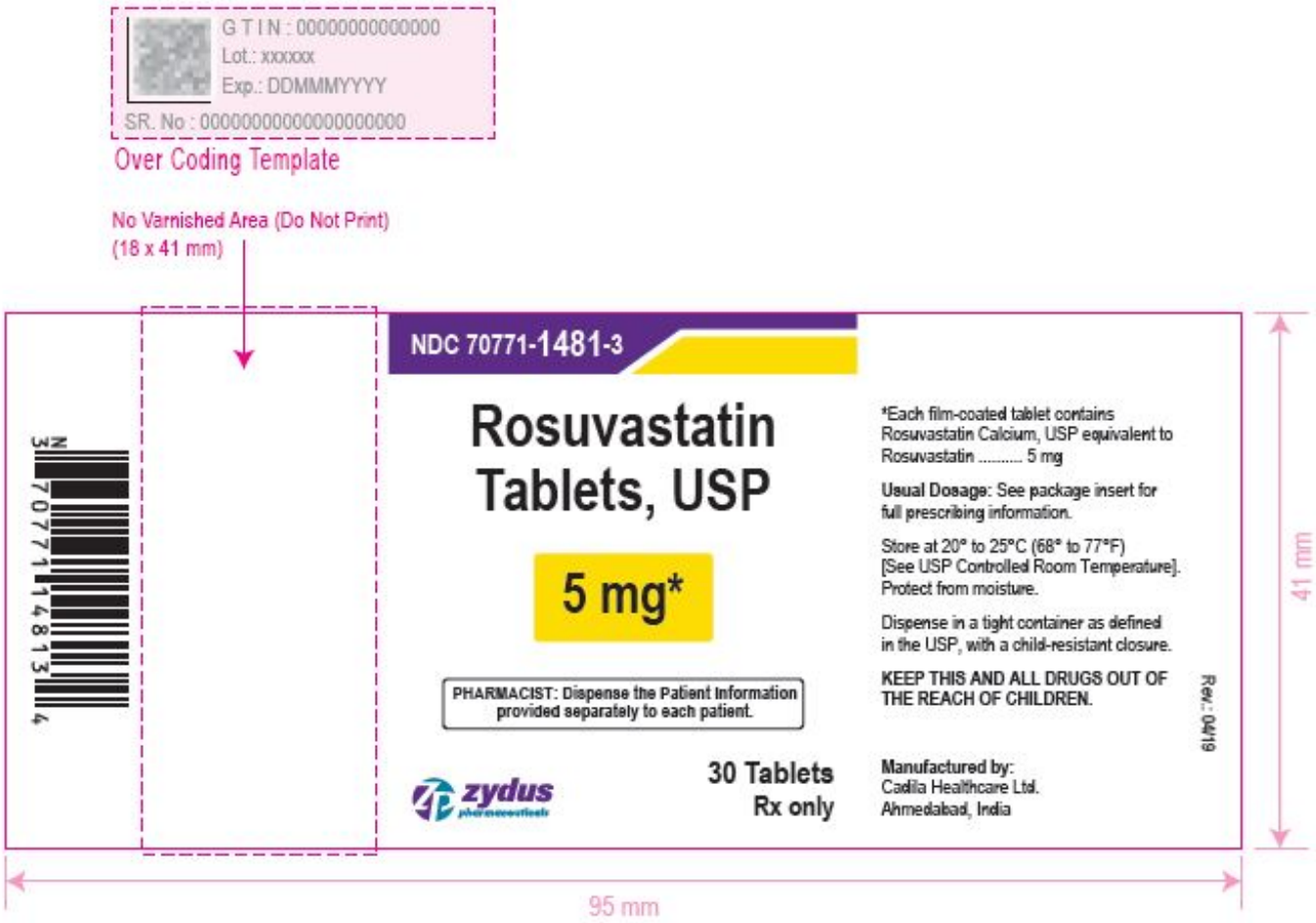
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1481-3

Rosuvastatin Calcium Tablets, 5 mg

30 Tablets

Rx only

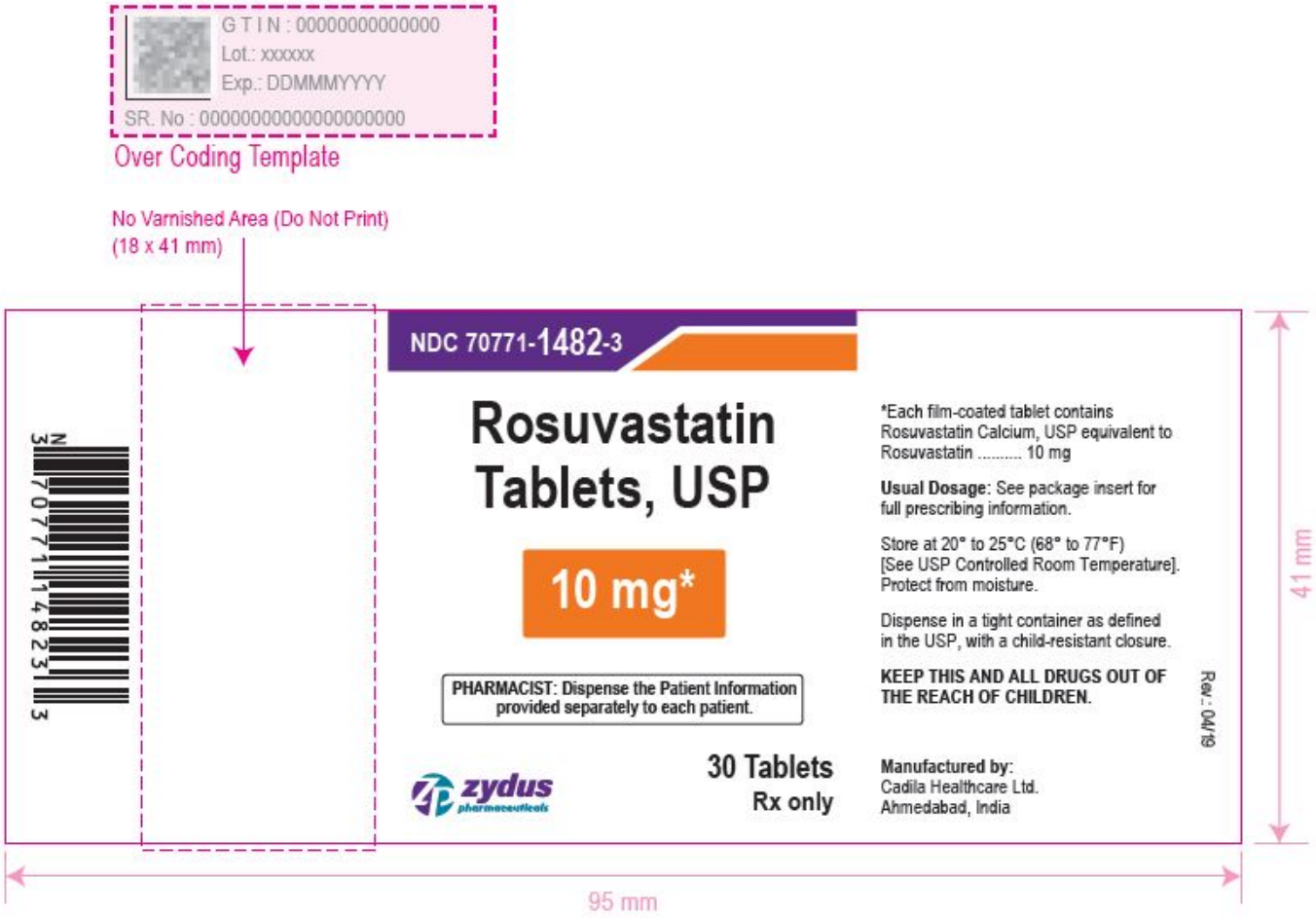


NDC 70771-1482-3

Rosuvastatin Calcium Tablets, 10 mg

30 Tablets

Rx only

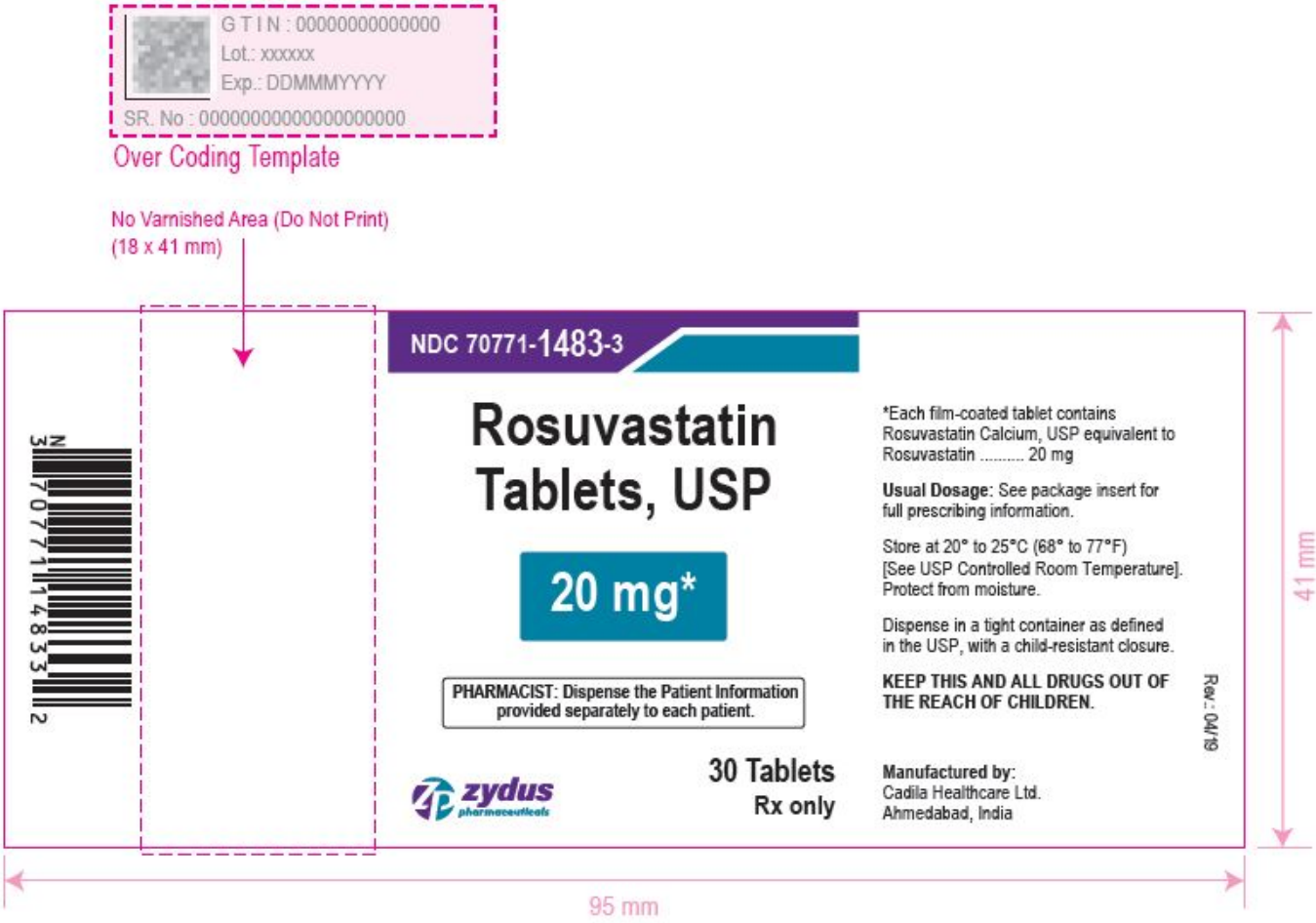


NDC 70771-1483-3

Rosuvastatin Calcium Tablets, 20 mg

30 Tablets

Rx only

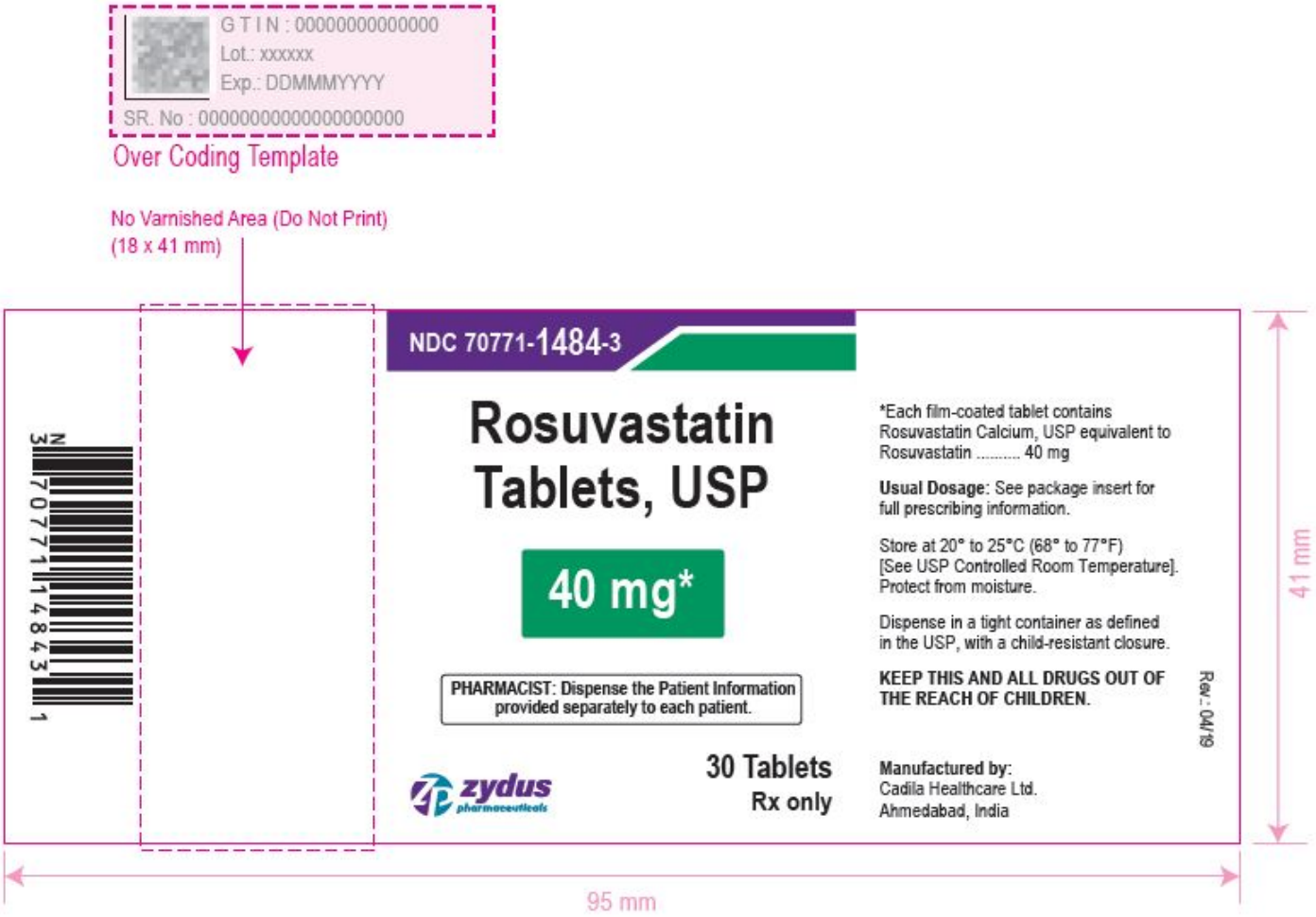


NDC 70771-1484-3

Rosuvastatin Calcium Tablets, 40 mg

30 Tablets

Rx only



ROSUVASTATIN

rosuvastatin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1481
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	627
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1481-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
2	NDC:70771-1481-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
3	NDC:70771-1481-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
4	NDC:70771-1481-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
5	NDC:70771-1481-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
6	NDC:70771-1481-2	10 in 1 CARTON	01/16/2020	07/09/2022
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206513	01/16/2020	07/09/2022

ROSUVASTATIN

rosuvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1482
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	10 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	PINK (PINK)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	628
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1482-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
2	NDC:70771-1482-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
3	NDC:70771-1482-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
4	NDC:70771-1482-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
5	NDC:70771-1482-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
6	NDC:70771-1482-2	10 in 1 CARTON	01/16/2020	07/09/2022
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206513	01/16/2020	07/09/2022

ROSUVASTATIN

rosuvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1483
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	ORANGE (ORANGE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	629
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1483-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	
2	NDC:70771-1483-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	
3	NDC:70771-1483-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	
4	NDC:70771-1483-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	
5	NDC:70771-1483-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	
6	NDC:70771-1483-2	10 in 1 CARTON	01/16/2020	

6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206513	01/16/2020	

ROSUVASTATIN

rosuvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1484
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ROSUVASTATIN CALCIUM (UNII: 83MVU38M7Q) (ROSUVASTATIN - UNII:413KH5ZJ73)	ROSUVASTATIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	PURPLE (LIGHT PURPLE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	16mm
Flavor		**Imprint Code**	630
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1484-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
2	NDC:70771-1484-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
3	NDC:70771-1484-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
4	NDC:70771-1484-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
5	NDC:70771-1484-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2020	07/09/2022
6	NDC:70771-1484-2	10 in 1 CARTON	01/16/2020	07/09/2022
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206513	01/16/2020	07/09/2022

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1481, 70771-1482, 70771-1483, 70771-1484) , MANUFACTURE(70771-1481, 70771-1482, 70771-1483, 70771-1484)

Revised: 7/2022 Zydus Lifesciences Limited