

ROSUVASTATIN - rosuvastatin tablet, film coated
Zydus Lifesciences Limited

ROSUVASTATIN TABLETS

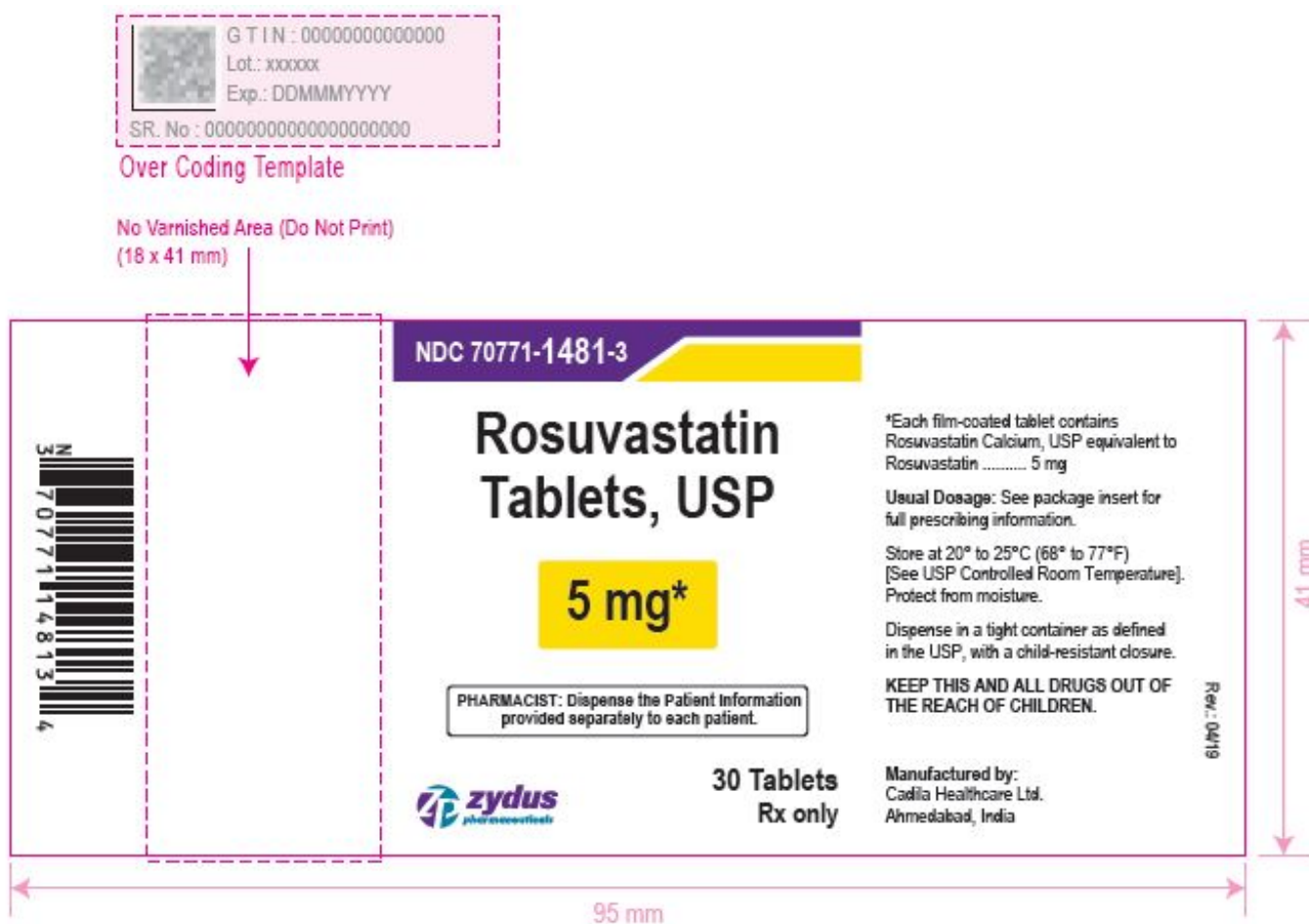
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

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

Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 70771-1482-3
Rosuvastatin Tablets, USP
10 mg*
30 Tablets Rx only

*Each film-coated tablet contains Rosuvastatin Calcium, USP equivalent to Rosuvastatin 10 mg
Usual Dosage: See package insert for full prescribing information.
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from moisture.
 Dispense in a tight container as defined in the USP, with a child-resistant closure.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

PHARMACIST: Dispense the Patient Information provided separately to each patient.

Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

Rev: 04/19

Dimensions: 95 mm (width) x 41 mm (height)

NDC 70771-1483-3

Rosuvastatin Calcium Tablets, 20 mg

30 Tablets

Rx only

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

Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

The image shows a rectangular product label for Rosuvastatin Tablets, USP 20 mg*. The label is 95 mm wide and 41 mm high. On the left side, there is a vertical barcode with the numbers 3, 7, 0, 7, 7, 1, 1, 4, 8, 3, 3, and 2. Above the barcode, the text 'NDC 70771-1483-3' is printed. The main text on the label reads 'Rosuvastatin Tablets, USP' in large, bold letters, followed by '20 mg*' in a blue box. Below this, there is a box containing the text 'PHARMACIST: Dispense the Patient Information provided separately to each patient.' The Zydus logo is located at the bottom left. On the right side, there is a block of text providing dosage and storage information: '*Each film-coated tablet contains Rosuvastatin Calcium, USP equivalent to Rosuvastatin 20 mg', 'Usual Dosage: See package insert for full prescribing information.', 'Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from moisture.', 'Dispense in a tight container as defined in the USP, with a child-resistant closure.', and 'KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.' The manufacturer information at the bottom right states 'Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India'. The text '30 Tablets Rx only' is printed at the bottom center. A vertical dimension line on the right indicates a height of 41 mm, and a horizontal dimension line at the bottom indicates a width of 95 mm. A red dashed box on the left side of the label indicates a 'No Varnished Area (Do Not Print) (18 x 41 mm)'.

NDC 70771-1484-3

Rosuvastatin Calcium Tablets, 40 mg

30 Tablets

Rx only



Over Coding Template

No Varnished Area (Do Not Print)
 (18 x 41 mm)

NDC 70771-1484-3

**Rosuvastatin
 Tablets, USP**

40 mg*

**30 Tablets
 Rx only**

**zydus
 pharmaceuticals**

PHARMACIST: Dispense the Patient Information provided separately to each patient.

Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

Rev: 04/19

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

Usual Dosage: See package insert for full prescribing information.

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

***Each film-coated tablet contains Rosuvastatin Calcium, USP equivalent to Rosuvastatin 40 mg**

Dimensions: 95 mm (width) x 41 mm (height)

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
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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)	
TRACETIN (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