

AMLODIPINE AND ATORVASTATIN - amlodipine and atorvastatin tablet, film coated

Zydus Lifesciences Limited

AMLODIPINE AND ATORVASTATIN Tablets

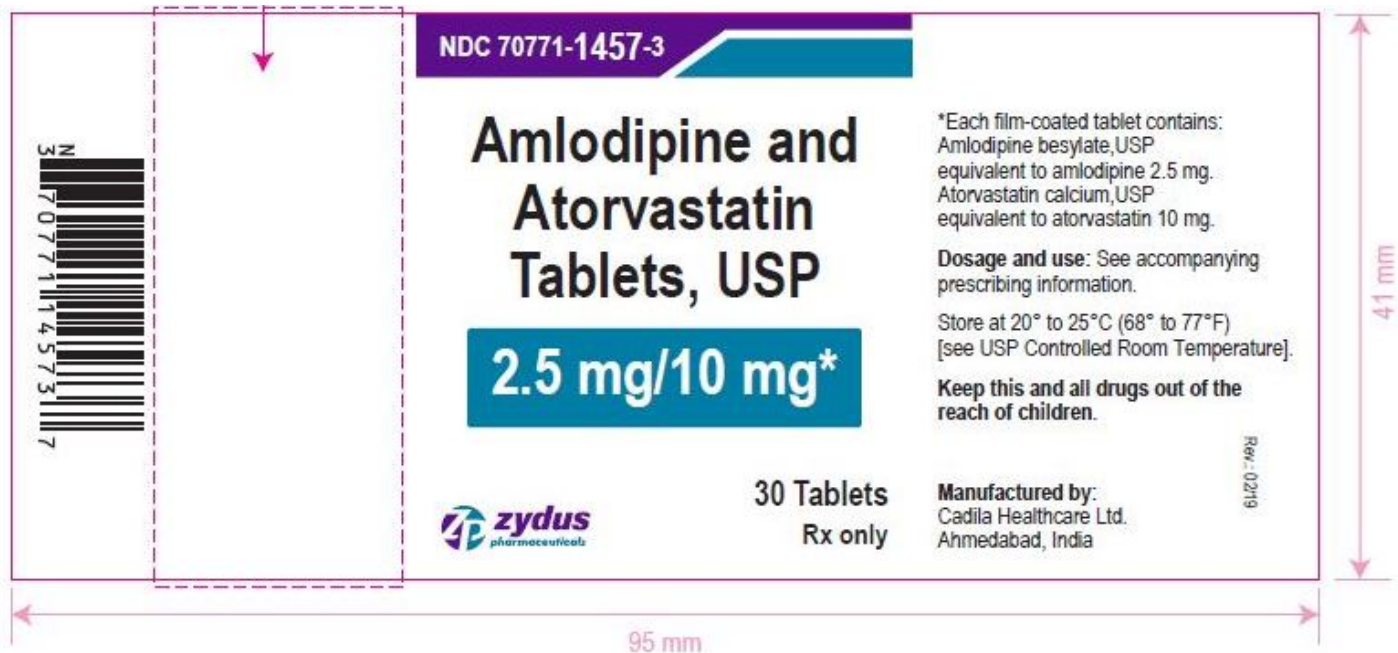
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1457-3

Amlodipine and atorvastatin tablets USP, 2.5 mg/ 10 mg

30 tablets

Rx only



NDC 70771-1458-3

Amlodipine and atorvastatin tablets USP, 2.5 mg/ 20 mg

30 tablets

Rx only

NDC 70771-1458-3

Amlodipine and Atorvastatin Tablets, USP

2.5 mg/20 mg*

30 Tablets
Rx only

zydus
pharmaceuticals

*Each film-coated tablet contains: Amlodipine besylate, USP equivalent to amlodipine 2.5 mg. Atorvastatin calcium, USP equivalent to atorvastatin 20 mg.

Dosage and use: See accompanying prescribing information.

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

Keep this and all drugs out of the reach of children.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 02/19

95 mm

41 mm

NDC 70771-1459-3

Amlodipine and atorvastatin tablets USP, 2.5 mg/ 40 mg

30 tablets

Rx only

NDC 70771-1459-3

Amlodipine and Atorvastatin Tablets, USP

2.5 mg/40 mg*

30 Tablets
Rx only

zydus
pharmaceuticals

*Each film-coated tablet contains: Amlodipine besylate, USP equivalent to amlodipine 2.5 mg. Atorvastatin calcium, USP equivalent to atorvastatin 40 mg.

Dosage and use: See accompanying prescribing information.

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

Keep this and all drugs out of the reach of children.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 02/19

95 mm

41 mm

NDC 70771-1460-3

Amlodipine and atorvastatin tablets USP, 5 mg/ 10 mg

30 tablets

Rx only



NDC 70771-1461-3

Amlodipine and atorvastatin tablets USP, 5 mg/ 20 mg

30 tablets

Rx only



NDC 70771-1462-3

Amlodipine and atorvastatin tablets USP, 5 mg/ 40 mg

30 tablets

Rx only

NDC 70771-1462-3

Amlodipine and Atorvastatin Tablets, USP

5 mg/40 mg*

30 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 02/19

*Each film-coated tablet contains:
Amlodipine besylate, USP
equivalent to amlodipine 5 mg.
Atorvastatin calcium, USP
equivalent to atorvastatin 40 mg.

Dosage and use: See accompanying
prescribing information.

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

**Keep this and all drugs out of the
reach of children.**

317077111462319

95 mm

41 mm

NDC 70771-1463-3

Amlodipine and atorvastatin tablets USP, 5 mg/ 80 mg

30 tablets

Rx only

NDC 70771-1463-3

Amlodipine and Atorvastatin Tablets, USP

5 mg/80 mg*

30 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 02/19

*Each film-coated tablet contains:
Amlodipine besylate, USP
equivalent to amlodipine 5 mg.
Atorvastatin calcium, USP
equivalent to atorvastatin 80 mg.

Dosage and use: See accompanying
prescribing information.

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

**Keep this and all drugs out of the
reach of children.**

317077111463318

95 mm

41 mm

NDC 70771-1464-3

Amlodipine and atorvastatin tablets USP, 10 mg/ 10 mg

30 tablets

Rx only

The label features a purple header with the NDC number 70771-1464-3. The main title 'Amlodipine and Atorvastatin Tablets, USP' is in large black font, with the strength '10 mg/10 mg*' highlighted in a green box. The Zydus logo is at the bottom left. The right side contains detailed text about the tablet's composition, dosage, storage, and safety. A barcode is on the left, and a vertical arrow points to the top edge. Dimensions of 95 mm width and 41 mm height are indicated.

NDC 70771-1464-3

Amlodipine and Atorvastatin Tablets, USP

10 mg/10 mg*

30 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 02/19

*Each film-coated tablet contains: Amlodipine besylate, USP equivalent to amlodipine 10 mg. Atorvastatin calcium, USP equivalent to atorvastatin 10 mg.

Dosage and use: See accompanying prescribing information.

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

Keep this and all drugs out of the reach of children.

95 mm

41 mm

NDC 70771-1465-3

Amlodipine and atorvastatin tablets USP, 10 mg/ 20 mg

30 tablets

Rx only

The label features a purple header with the NDC number 70771-1465-3. The main title 'Amlodipine and Atorvastatin Tablets, USP' is in large black font, with the strength '10 mg/20 mg*' highlighted in a blue box. The Zydus logo is at the bottom left. The right side contains detailed text about the tablet's composition, dosage, storage, and safety. A barcode is on the left, and a vertical arrow points to the top edge. Dimensions of 95 mm width and 41 mm height are indicated.

NDC 70771-1465-3

Amlodipine and Atorvastatin Tablets, USP

10 mg/20 mg*

30 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 02/19

*Each film-coated tablet contains: Amlodipine besylate, USP equivalent to amlodipine 10 mg. Atorvastatin calcium, USP equivalent to atorvastatin 20 mg.

Dosage and use: See accompanying prescribing information.

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

Keep this and all drugs out of the reach of children.

95 mm

41 mm

NDC 70771-1466-3

Amlodipine and atorvastatin tablets USP, 10 mg/ 40 mg

30 tablets

Rx only

The image shows a rectangular product label with a white background and purple accents. On the left side, there is a vertical barcode with the number 'N' above it and '7077114663' printed vertically. Below the barcode is the number '5'. At the top left, a purple banner contains the NDC number 'NDC 70771-1466-3'. The main title 'Amlodipine and Atorvastatin Tablets, USP' is centered in large black font. Below the title, a purple box contains the text '10 mg/40 mg*'. The Zydus logo is at the bottom left. The text '30 Tablets' and 'Rx only' is positioned at the bottom center. On the right side, there is a block of text providing details about the tablet's composition, dosage, storage, and safety. 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.

NDC 70771-1466-3

Amlodipine and Atorvastatin Tablets, USP

10 mg/40 mg*

30 Tablets
Rx only

zydus
pharmaceuticals

*Each film-coated tablet contains:
Amlodipine besylate, USP
equivalent to amlodipine 10 mg.
Atorvastatin calcium, USP
equivalent to atorvastatin 40 mg.

Dosage and use: See accompanying
prescribing information.

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

**Keep this and all drugs out of the
reach of children.**

Rev: 02/19

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

95 mm

41 mm


NDC 70771-1467-3

Amlodipine and atorvastatin tablets USP, 10 mg/80 mg

30 tablets


Rx only

NDC 70771-1467-3



Amlodipine and Atorvastatin Tablets, USP

10 mg/80 mg*



*Each film-coated tablet contains: Amlodipine besylate, USP equivalent to amlodipine 10 mg. Atorvastatin calcium, USP equivalent to atorvastatin 80 mg.

Dosage and use: See accompanying prescribing information.

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

Keep this and all drugs out of the reach of children.

Rev: 02/19

30 Tablets
Rx only

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

95 mm

41 mm

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1467
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	10 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	80 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (BLUE)	Score	no score
Shape	OVAL (BICONVEX)	Size	17mm
Flavor		Imprint Code	F14
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1467-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1467-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1467-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1467-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1457
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	2.5 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
HYPROMELLOSES (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STARCH, CORN (UNII: O8232NY3SJ)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	424
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1457-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1457-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1457-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1457-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1458
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	2.5 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	425
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1458-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1458-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1458-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1458-4	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1459
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	2.5 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	426
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1459-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1459-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1459-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1459-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1460
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	5 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	9mm
Flavor		Imprint Code	427
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:70771-1460-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1460-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1460-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1460-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1461
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	5 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	11mm
Flavor		Imprint Code	428
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1461-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1461-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1461-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1461-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1462
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	5 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)

HYPROMELLOSES (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6I3O)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

STARCH, CORN (UNII: O8232NY3SJ)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	14mm
Flavor		Imprint Code	429
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1462-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1462-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1462-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1462-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1463
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	5 mg		
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	80 mg		
Inactive Ingredients				
Ingredient Name		Strength		
CALCIUM CARBONATE (UNII: H0G9379FGK)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score	
Shape	OVAL (OVAL)	Size	17mm	
Flavor		Imprint Code	430	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1463-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1463-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1463-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1463-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019		

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1464
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	10 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (LIGHT BLUE TO BLUE)	Score	no score
Shape	OVAL (o)	Size	11mm
Flavor		Imprint Code	431
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1464-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1464-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1464-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1464-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1465
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	10 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (LIGHT BLUE TO BLUE)	Score	no score
Shape	OVAL (OVAL)	Size	11mm
Flavor		Imprint Code	432
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1465-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1465-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1465-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1465-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

AMLODIPINE AND ATORVASTATIN

amlodipine and atorvastatin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1466
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	10 mg
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (LIGHT BLUE TO BLUE)	Score	no score
Shape	OVAL (OVAL)	Size	14mm
Flavor		Imprint Code	433
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1466-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
2	NDC:70771-1466-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
3	NDC:70771-1466-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	
4	NDC:70771-1466-4	10 in 1 CARTON	05/30/2019	
4		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	ANDA207762	05/30/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1457, 70771-1458, 70771-1459, 70771-1460, 70771-1461, 70771-1462, 70771-1463, 70771-1464, 70771-1465, 70771-1466, 70771-1467) , MANUFACTURE(70771-1457, 70771-1458, 70771-1459, 70771-1460, 70771-1461, 70771-1462, 70771-1463, 70771-1464, 70771-1465, 70771-1466, 70771-1467)

Revised: 10/2022

Zydus Lifesciences Limited