

ATORVASTATIN CALCIUM- atorvastatin calcium tablet
Zydus Lifesciences Limited

ATORVASTATIN CALCIUM tablets, for oral use

NDC 70771-1875-9

Atorvastatin Calcium Tablets, USP 10 mg

Rx Only

90 Tablets



NDC 70771-1876-9

Atorvastatin Calcium Tablets, USP 20 mg

Rx Only

90 Tablets

31707101177591

Rev.: 06/24

Atorvastatin Calcium Tablets, USP

20 mg*

zydUS

90 Tablets
Rx only

*Each film-coated tablet contains atorvastatin calcium, USP equivalent to 20 mg atorvastatin.
Usual Dosage: See package insert for full prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
 Dispense in tight containers (USP).
Keep this and all drugs out of the reach of children.
Manufactured by:
 Zydus Lifesciences Ltd.
 Ahmedabad, India

NDC 70771-1877-9

Atorvastatin Calcium Tablets, USP 40 mg

Rx Only

90 Tablets

31707101177294

Rev.: 06/24

Atorvastatin Calcium Tablets, USP

40 mg*

zydUS

90 Tablets
Rx only

*Each film-coated tablet contains atorvastatin calcium, USP equivalent to 40 mg atorvastatin.
Usual Dosage: See package insert for full prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
 Dispense in tight containers (USP).
Keep this and all drugs out of the reach of children.
Manufactured by:
 Zydus Lifesciences Ltd.
 Ahmedabad, India

NDC 70771-1878-9

Atorvastatin Calcium Tablets, USP 80 mg

Rx Only

90 Tablets

3
707101177091
6

Rev.: 06/24

**Atorvastatin
Calcium
Tablets, USP**

80 mg*

zydus

90 Tablets
Rx only

*Each film-coated tablet contains atorvastatin calcium, USP equivalent to 80 mg atorvastatin.
Usual Dosage: See package insert for full prescribing information.
This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
 Dispense in tight containers (USP).
Keep this and all drugs out of the reach of children.
Manufactured by:
 Zydus Lifesciences Ltd.
 Ahmedabad, India

ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1875
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	OVAL (OVAL)	Size	8mm
Flavor		Imprint Code	1777
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1875-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
2	NDC:70771-1875-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
3	NDC:70771-1875-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	06/12/2024	

ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1876
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	OVAL (OVAL)	Size	10mm
Flavor		Imprint Code	1775
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1876-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
2	NDC:70771-1876-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
3	NDC:70771-1876-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	06/12/2024	

ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1877
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
HYPROMELLOSES (UNII: 3NXW29V3WO)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE SODIUM PHOSPHATE (UNII: E6S1NJ4Y5Q)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	OVAL (OVAL)	Size	13mm
Flavor		Imprint Code	1772
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1877-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
2	NDC:70771-1877-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
3	NDC:70771-1877-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	06/12/2024	

ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1878
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATORVASTATIN CALCIUM TRIHYDRATE (UNII: 48A5M73Z4Q) (ATORVASTATIN - UNII:A0JWA85V8F)	ATORVASTATIN	80 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	OVAL (OVAL)	Size	17mm
Flavor		Imprint Code	1770
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1878-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
2	NDC:70771-1878-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	
3	NDC:70771-1878-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	06/12/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1875, 70771-1876, 70771-1877, 70771-1878) , MANUFACTURE(70771-1875, 70771-1876, 70771-1877, 70771-1878)

