

ATORVASTATIN CALCIUM- atorvastatin calcium tablet
Zydus Lifesciences Limited

ATORVASTATIN CALCIUM TABLETS.

NDC 70771-1443-3

Atorvastatin Calcium Tablets, USP 10 mg

Rx Only

30 Tablets



NDC 70771-1444-3

Atorvastatin Calcium Tablets, USP 20 mg

Rx Only

30 Tablets

NDC 70771-1444-3

Atorvastatin Calcium Tablets, USP

20 mg*

250

30 Tablets
Rx only

zydus
pharmaceuticals

*Each film-coated tablet contains atorvastatin calcium, USP equivalent to 20 mg atorvastatin.

Usual Dosage: See package insert for full prescribing information.

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

Dispense in tight containers (USP).

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

Rev: 11/18

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

95 mm

41 mm

NDC 70771-1445-3

Atorvastatin Calcium Tablets, USP 40 mg

Rx Only

30 Tablets

NDC 70771-1445-3

Atorvastatin Calcium Tablets, USP

40 mg*

251

30 Tablets
Rx only

zydus
pharmaceuticals

*Each film-coated tablet contains atorvastatin calcium, USP equivalent to 40 mg atorvastatin.

Usual Dosage: See package insert for full prescribing information.

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

Dispense in tight containers (USP).

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

Rev: 11/18

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

95 mm

41 mm

NDC 70771-1446-3

Atorvastatin Calcium Tablets, USP 80 mg

Rx Only

30 Tablets



ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1443
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
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	9mm
Flavor		Imprint Code	249
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1443-4	10 in 1 CARTON	11/21/2018	04/01/2026
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1443-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
3	NDC:70771-1443-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
4	NDC:70771-1443-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
5	NDC:70771-1443-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
6	NDC:70771-1443-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	11/21/2018	04/01/2026

ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1444
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 (110000 WAMW) (UNII: 5Y0974F5PW)	
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	11mm
Flavor		Imprint Code	250
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1444-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
2	NDC:70771-1444-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
3	NDC:70771-1444-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
4	NDC:70771-1444-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
5	NDC:70771-1444-4	10 in 1 CARTON	11/21/2018	04/01/2026
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:70771-1444-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	11/21/2018	04/01/2026

ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1445
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
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	14mm
Flavor		Imprint Code	251
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1445-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
2	NDC:70771-1445-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
3	NDC:70771-1445-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
4	NDC:70771-1445-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
5	NDC:70771-1445-4	10 in 1 CARTON	11/21/2018	04/01/2026
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:70771-1445-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	11/21/2018	04/01/2026

ATORVASTATIN CALCIUM

atorvastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1446
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
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	19mm
Flavor		Imprint Code	252
Contains			

Packaging

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

1	NDC:70771-1446-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
2	NDC:70771-1446-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
3	NDC:70771-1446-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
4	NDC:70771-1446-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026
5	NDC:70771-1446-4	10 in 1 CARTON	11/21/2018	04/01/2026
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:70771-1446-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	04/01/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206536	11/21/2018	04/01/2026

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1443, 70771-1444, 70771-1445, 70771-1446) , MANUFACTURE(70771-1443, 70771-1444, 70771-1445, 70771-1446)

Revised: 10/2024

Zydus Lifesciences Limited