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

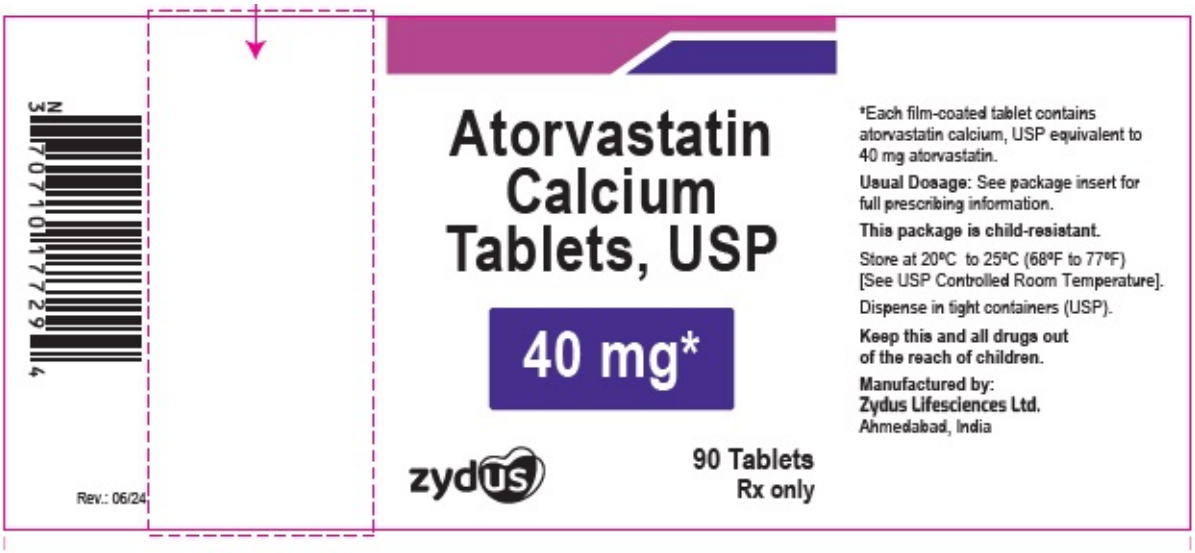
90 Tablets

NDC 70771-1877-9

Atorvastatin Calcium Tablets, USP 40 mg

Rx Only

90 Tablets

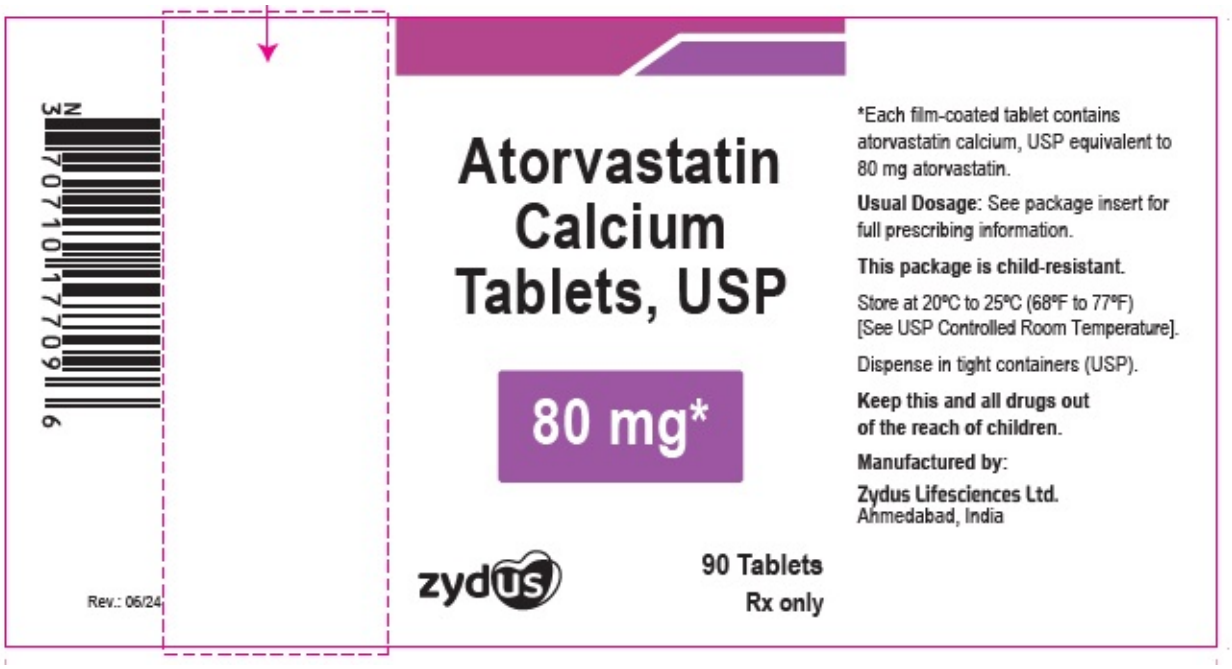


NDC 70771-1878-9

Atorvastatin Calcium Tablets, USP 80 mg

Rx Only

90 Tablets



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: 3WQ0SDW1A)	
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)	
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: 3WQ0SDW1A)	
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: 3WQ0SDW1A)	
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)	
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: 3WQ0SDW1A)	
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)