ATORVASTATIN CALCIUM- atorvastatin calcium tablet
Cadila Healthcare 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 70771-1445-3

Atorvastatin Calcium Tablets, USP 40 mg

Rx Only

30 Tablets

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)	
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**	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	
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	
3	NDC:70771-1443-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
4	NDC:70771-1443-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
5	NDC:70771-1443-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
6	NDC:70771-1443-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	

Marketing Information

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

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)	
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**	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	
2	NDC:70771-1444-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
3	NDC:70771-1444-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
4	NDC:70771-1444-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
5	NDC:70771-1444-4	10 in 1 CARTON	11/21/2018	
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	

Marketing Information

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

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)	

CROSCARMELLOSE 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	
2	NDC:70771-1445-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
3	NDC:70771-1445-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
4	NDC:70771-1445-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
5	NDC:70771-1445-4	10 in 1 CARTON	11/21/2018	
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	

Marketing Information

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

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	
2	NDC:70771-1446-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
3	NDC:70771-1446-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
4	NDC:70771-1446-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	
5	NDC:70771-1446-4	10 in 1 CARTON	11/21/2018	
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	

Marketing Information

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

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare		863262780	ANALYSIS(70771-1443, 70771-1444, 70771-1445, 70771-1446) , MANUFACTURE(70771-

Limited		68382789	1443, 70771-1444, 70771-1445, 70771-1446)