

**ATORVASTATIN CALCIUM- atorvastatin calcium tablet**  
**Zydus Lifesciences Limited**

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**ATORVASTATIN CALCIUM tablets, for oral use**

NDC 70771-1875-9

Atorvastatin Calcium Tablets, USP 10 mg

Rx Only

90 Tablets

The image shows the front of a white rectangular box for Atorvastatin Calcium Tablets, USP 10 mg\*. The box features a purple and teal header. On the left side, there is a vertical barcode with the number 'N 70710117779 9' printed vertically. Below the barcode, it says 'Rev.: 06/24'. The main text on the box reads 'Atorvastatin Calcium Tablets, USP' in large black font, with '10 mg\*' in white text on a teal background. Below this, the 'zydus' logo is visible. To the right of the logo, it says '90 Tablets Rx only'. On the far right, there is a block of text providing dosage and storage information: '\*Each film-coated tablet contains atorvastatin calcium, USP equivalent to 10 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 70771-1876-9

Atorvastatin Calcium Tablets, USP 20 mg

Rx Only

90 Tablets

31  
N  
707101177591  
1

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

31  
N  
707101177294  
4

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



Rev.: 06/24

# Atorvastatin Calcium Tablets, USP

80 mg\*



**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

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

## Product Characteristics

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

## 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

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

**POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ05DW1A)

**POLYSORBATE 80** (UNII: 6OZP39ZG8H)

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

**TALC** (UNII: 7SEV7J4R1U)

### Product Characteristics

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

### 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

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

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	

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

### Product Characteristics

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

### 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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ATORVASTATIN CALCIUM TRIHYDRATE</b> (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: 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)

