

PITAVASTATIN CALCIUM- pitavastatin calcium tablet
Zydus Lifesciences Limited

These highlights do not include all the information needed to use PITAVASTATIN TABLETS safely and effectively. See full prescribing information for PITAVASTATIN TABLETS.

PITAVASTATIN tablets, for oral use
Initial U.S. Approval: 2009

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Pitavastatin Tablets, 1 mg

NDC 70771-1784-9

Bottle of 90 tablets

Rx only

NDC 70771-1784-9

**Pitavastatin
Tablets**

1 mg

zydus 90 Tablets
Rx only

Each film-coated tablet contains 1.045 mg of pitavastatin calcium equivalent to 1 mg of pitavastatin.

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].

Protect from moisture and light. Dispense in an appropriate tight, light-resistant, child-resistant container.

Keep this and all drugs out of the reach of children.

Manufactured by:
Zydus Lifesciences Ltd., Ahmedabad, India

Rev.:03/23

Pitavastatin Tablets, 2 mg

NDC 70771-1785-9

Bottle of 90 tablets

Rx only

NDC 70771-1785-9

**Pitavastatin
Tablets**

2 mg

zydUS 90 Tablets
Rx only

Each film-coated tablet contains 2.09 mg of pitavastatin calcium equivalent to 2 mg of pitavastatin.

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].

Protect from moisture and light. Dispense in an appropriate tight, light-resistant, child-resistant container.

Keep this and all drugs out of the reach of children.

Manufactured by:
Zydus Lifesciences Ltd., Ahmedabad, India

Rev.:03/23

Pitavastatin Tablets, 4 mg
 NDC 70771-1786-9
 Bottle of 90 tablets
 Rx only

NDC 70771-1786-9

**Pitavastatin
Tablets**

4 mg

zydUS 90 Tablets
Rx only

Each film-coated tablet contains 4.18 mg of pitavastatin calcium equivalent to 4 mg of pitavastatin.

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].

Protect from moisture and light. Dispense in an appropriate tight, light-resistant, child-resistant container.

Keep this and all drugs out of the reach of children.

Manufactured by:
Zydus Lifesciences Ltd., Ahmedabad, India

Rev.:03/23

PITAVASTATIN CALCIUM

pitavastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1784
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PITAVASTATIN CALCIUM (UNII: IYD54XEG3W) (PITAVASTATIN - UNII:M5681Q5F9P)	PITAVASTATIN	1 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSPROVIDONE (120 .MU.M) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	481
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1784-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206047	11/02/2023	

PITAVASTATIN CALCIUM

pitavastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1785
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PITAVASTATIN CALCIUM (UNII: IYD54XEG3W) (PITAVASTATIN - UNII:M5681Q5F9P)	PITAVASTATIN	2 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSPROVIDONE (120 .MU.M) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	482
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1785-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206047	11/02/2023	

PITAVASTATIN CALCIUM

pitavastatin calcium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1786
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PITAVASTATIN CALCIUM (UNII: IYD54XEG3W) (PITAVASTATIN - UNII:M5681Q5F9P)	PITAVASTATIN	4 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSPROVIDONE (120 .MU.M) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	483
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1786-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206047	11/02/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
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Zydus Lifesciences
Limited

918596198

ANALYSIS(70771-1784, 70771-1785, 70771-1786) , MANUFACTURE(70771-1784, 70771-1785, 70771-1786)

Revised: 12/2024

Zydus Lifesciences Limited