

ZYPITAMAG- pitavastatin magnesium tablet, film coated
Zydus Lifesciences Limited

ZYPITAMAG (pitavastatin) tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1117-9

Zypitamag (Pitavastatin) Tablets, 2 mg

90 Tablets

Rx only

NDC 70771-1117-9

**Zypitamag
(Pitavastatin)
Tablets**

2 mg

**90 Tablets
Rx only**

Each film-coated tablet contains 2.053 mg of pitavastatin magnesium 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

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04/2017/1117-9
Z12-80-90-03

NDC 70771-1118-9

Zypitamag (Pitavastatin) Tablets, 4 mg

90 Tablets

Rx only

NDC 70771-1118-9

**Zypitamag
(Pitavastatin)
Tablets**

4 mg

90 Tablets
Rx only

Each film-coated tablet contains 4.106 mg of pitavastatin magnesium 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].

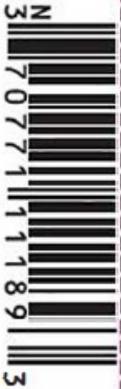
Protect from moisture and light. Dispense in an appropriate tight, light-resistant, child-resistant container.

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

Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India

G1402001-006

ZV4-B0-90-03




ZYPITAMAG

pitavastatin magnesium tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1117
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSPROVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (off white)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	877

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1117-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
2	NDC:70771-1117-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
3	NDC:70771-1117-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
4	NDC:70771-1117-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
5	NDC:70771-1117-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
6	NDC:70771-1117-4	10 in 1 CARTON	03/09/2018	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:70771-1117-7	1 in 1 CARTON	03/09/2018	
7		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208379	03/09/2018	

ZYPITAMAG

pitavastatin magnesium tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1118
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (off white)	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	878
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1118-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
2	NDC:70771-1118-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
3	NDC:70771-1118-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
4	NDC:70771-1118-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
5	NDC:70771-1118-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2018	
6	NDC:70771-1118-4	10 in 1 CARTON	03/09/2018	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:70771-1118-7	1 in 1 CARTON	03/09/2018	
7		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208379	03/09/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences		918596198	ANALYSIS(70771-1117, 70771-1118) , MANUFACTURE(70771-1117,

Revised: 8/2024

Zydus Lifesciences Limited