

OMEPRAZOLE- omeprazole capsule, delayed release
Zydus Lifesciences Limited

OMEPRAZOLE DELAYED-RELEASE CAPSULES, USP

SPL MEDGUIDE

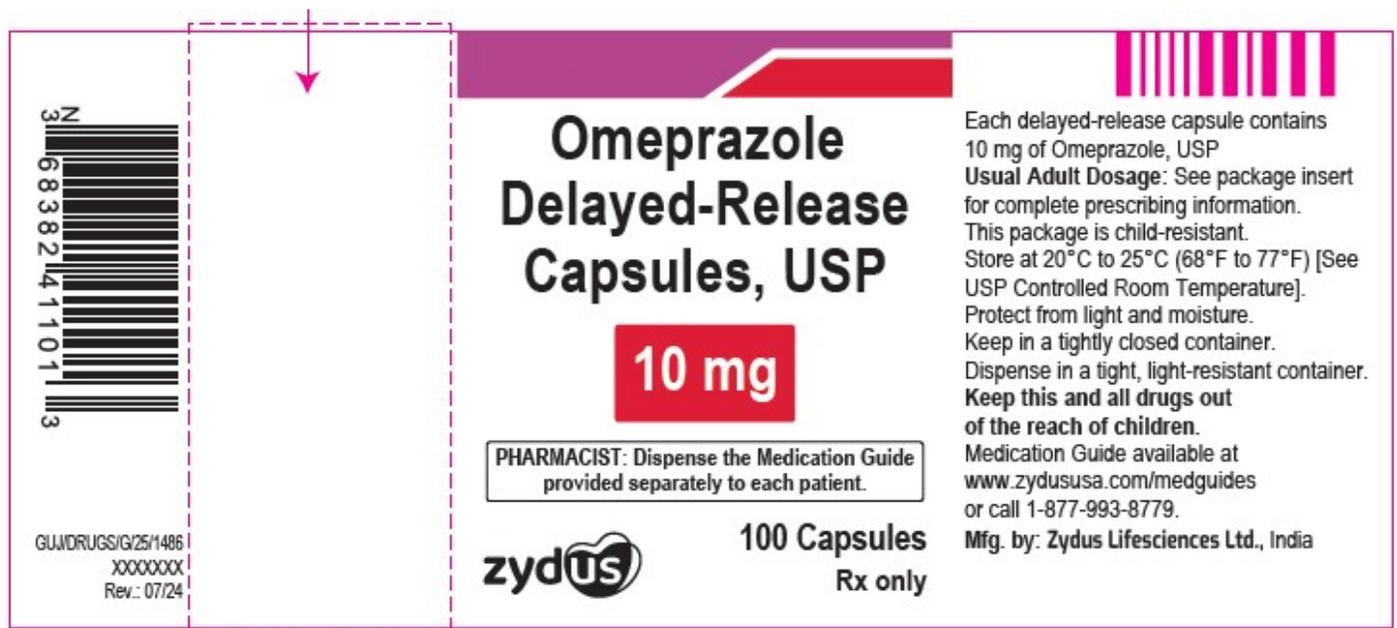
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-759-01 in bottle of 100 Capsules

Omeprazole Delayed-release Capsules USP, 10 mg

R_x only

100 Capsules



NDC 65841-760-01 in bottle of 100 Capsules

Omeprazole Delayed-release Capsules USP, 20 mg

R_x only

100 Capsules

3
N
68382141201
0

GUJIDRUGS/G/25/1486
XXXXXXX
Rev.: 07/24

Omeprazole Delayed-Release Capsules, USP

20 mg

PHARMACIST: Dispense the Medication Guide
provided separately to each patient.

zydus

100 Capsules
Rx only

Each delayed-release capsule contains 20 mg of Omeprazole, USP
Usual Adult Dosage: See package insert for complete 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 light and moisture.
 Keep in a tightly closed container.
 Dispense in a tight, light-resistant container.
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides
 or call 1-877-993-8779.
 Mfg. by: Zydus Lifesciences Ltd., India

NDC 65841-761-01 in bottle of 100 Capsules

Omeprazole Delayed-release Capsules USP, 40 mg

R_x only

100 Capsules

3
N
6838250001
4

GUJIDRUGS/G/25/1486
XXXXXXX
Rev.: 07/24

Omeprazole Delayed-Release Capsules, USP

40 mg

PHARMACIST: Dispense the
Medication Guide provided
separately to each patient.

zydus

100 Capsules
Rx only

Each delayed-release capsule contains 40 mg of Omeprazole, USP
Usual Adult Dosage: See package insert for complete 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 light and moisture.
 Keep in a tightly closed container.
 Dispense in a tight, light-resistant container.
Keep this and all drugs out of the reach of children.
 Medication Guide available at www.zydususa.com/medguides
 or call 1-877-993-8779.
 Mfg. by: Zydus Lifesciences Ltd., India

OMEPRAZOLE

omeprazole capsule, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-759
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRazole (UNII: KG60484QX9) (OMEPRazole - UNII:KG60484QX9)	OMEPRazole	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACETONE (UNII: 1364PS73AF)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (160000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST) (UNII: 8LDD2V82F5)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	PURPLE (AMETHYST PURPLE) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	10mm
Flavor		Imprint Code	ZA;09;10mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-759-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
2	NDC:65841-759-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
3	NDC:65841-759-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	

4	NDC:65841-759-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
5	NDC:65841-759-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091352	11/23/2012	

OMEPRAZOLE

omeprazole capsule, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-760
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
ACETONE (UNII: 1364PS73AF)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST) (UNII: 8LDD2V82F5)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics				
Color	BROWN (TAN) , WHITE (WHITE)	Score	no score	
Shape	CAPSULE (CAPSULE)	Size	11mm	
Flavor		Imprint Code	ZA;10;20mg	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-760-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
2	NDC:65841-760-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
3	NDC:65841-760-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
4	NDC:65841-760-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
5	NDC:65841-760-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA091352	11/23/2012		

OMEPRAZOLE			
omeprazole capsule, delayed release			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-761
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)		OMEPRAZOLE	40 mg
Inactive Ingredients			
Ingredient Name			Strength
ACETONE (UNII: 1364PS73AF)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)			
FERROSFERRIC OXIDE (UNII: XM0M87F357)			
GELATIN (UNII: 2G86QN327L)			

HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST) (UNII: 8LDD2V82F5)
HYPROMELLOSES (UNII: 3NXW29V3WO)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B71O)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)
SUCROSE (UNII: C151H8M554)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	PURPLE (AMETHYST PURPLE) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	19mm
Flavor		Imprint Code	ZA;11;40mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-761-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
2	NDC:65841-761-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
3	NDC:65841-761-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
4	NDC:65841-761-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	
5	NDC:65841-761-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091352	11/23/2012	

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(65841-759, 65841-760, 65841-761) , MANUFACTURE(65841-759, 65841-760, 65841-761)
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Revised: 12/2024

Zydus Lifesciences Limited