OMEPRAZOLE AND SODIUM BICARBONATE- omeprazole and sodium bicarbonate capsule
Zydus Lifesciences Limited

OMEPRAZOLE AND SODIUM BICARBONATE CAPSULES

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

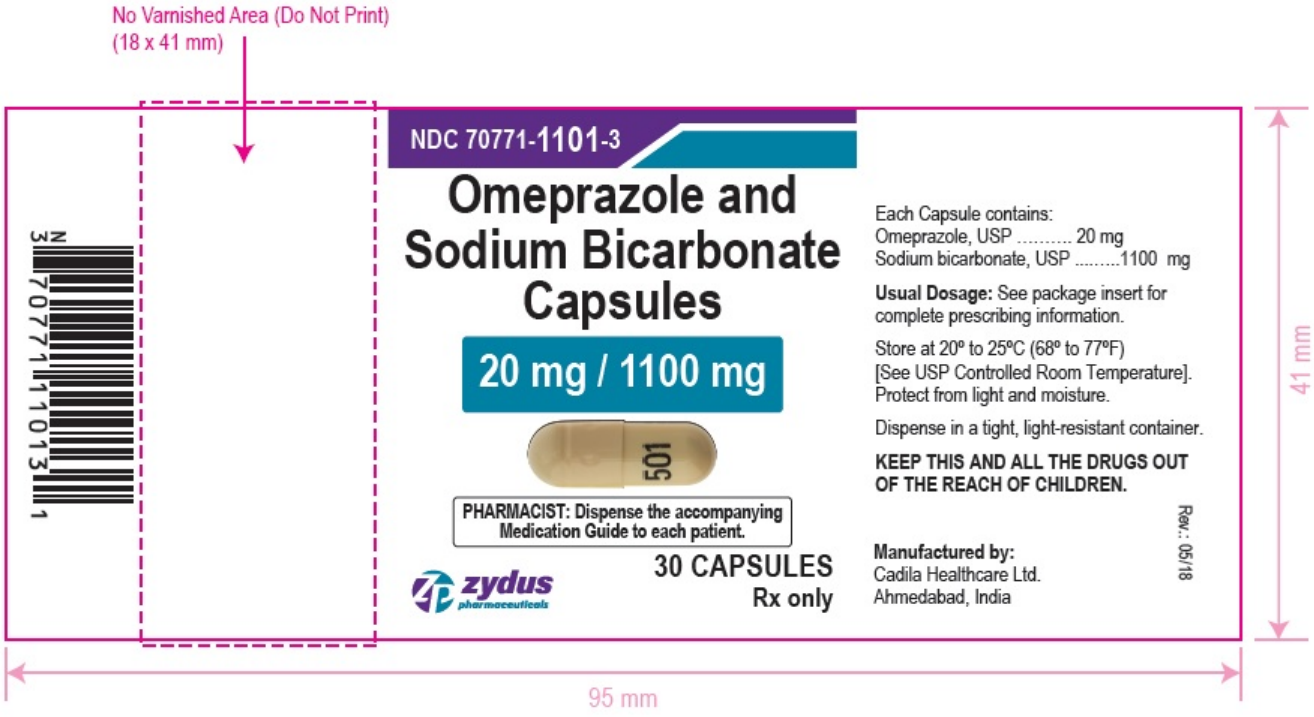
NDC 70771-1101-3 in bottle of 30 capsules

Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg

R_x only

30 capsules

ZYDUS



NDC 70771-1102-3 in bottle of 30 capsules

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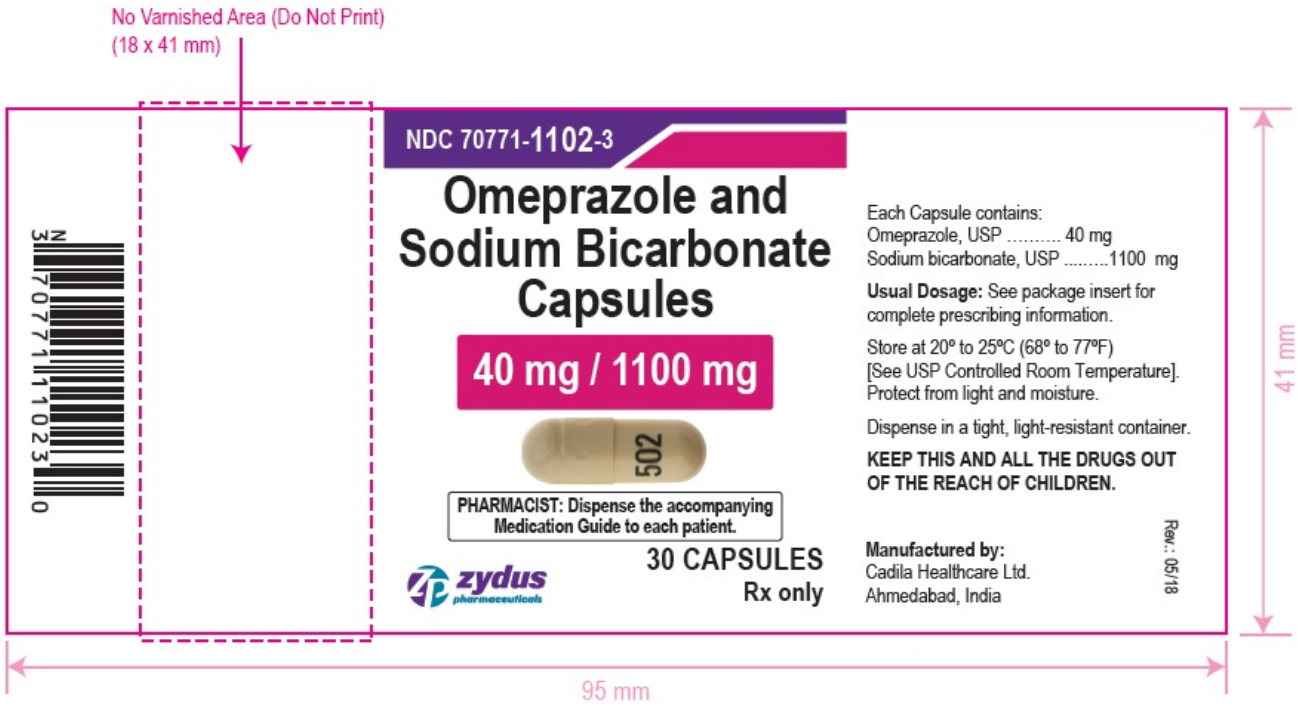
Omeprazole and Sodium Bicarbonate Capsules, 40 mg/1100 mg

R_x only

30 capsules

ZYDUS



OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole and sodium bicarbonate capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1101
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1100 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	WHITE (OPAQUE WHITE) , WHITE (OPAQUE WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	23mm
Flavor		**Imprint Code**	501
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1101-7	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
2	NDC:70771-1101-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
3	NDC:70771-1101-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
4	NDC:70771-1101-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
5	NDC:70771-1101-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
6	NDC:70771-1101-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
7	NDC:70771-1101-4	10 in 1 CARTON	05/29/2018	
7	NDC:70771-1101-2	10 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

ANDA	ANDA203290	05/29/2018	

OMEPRAZOLE AND SODIUM BICARBONATE

omeprazole and sodium bicarbonate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	40 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1100 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
ALCOHOL (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	WHITE (OPAQUE WHITE) , WHITE (OPAQUE WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	23mm
Flavor		**Imprint Code**	502
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-	30 in 1 BOTTLE; Type 0: Not a Combination	05/29/2018	

1	1102-3	Product	05/29/2018	
2	NDC:70771-1102-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
3	NDC:70771-1102-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
4	NDC:70771-1102-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
5	NDC:70771-1102-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/29/2018	
6	NDC:70771-1102-4	10 in 1 CARTON	05/29/2018	
6	NDC:70771-1102-2	10 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
ANDA	ANDA203290	05/29/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1101, 70771-1102) , MANUFACTURE(70771-1101, 70771-1102)

Revised: 9/2023 Zydus Lifesciences Limited