LENALIDOMIDE- lenalidomide capsule
Zydus Lifesciences Limited

LENALIDOMIDE capsules, for oral use

SPL MEDGUIDE

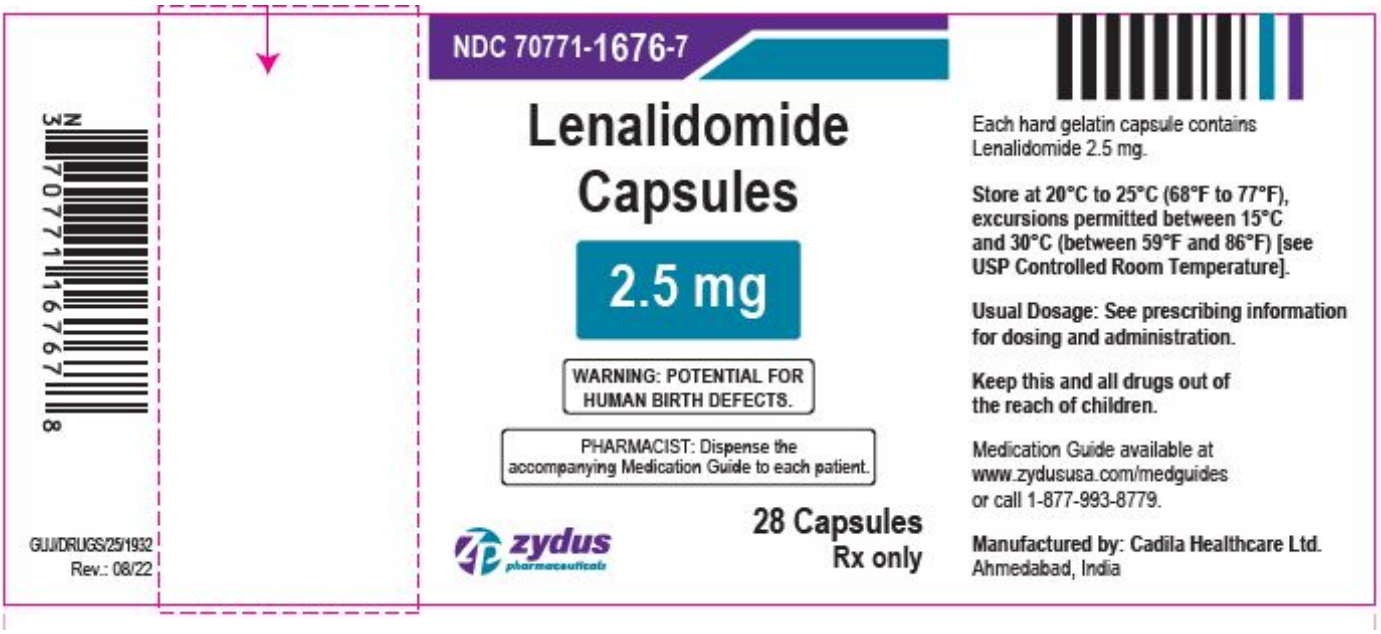
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1676-7

Lenalidomide Capsules, 2.5 mg

28 Capsules

Rx only



NDC 70771-1677-7

Lenalidomide Capsules, 5 mg

28 Capsules

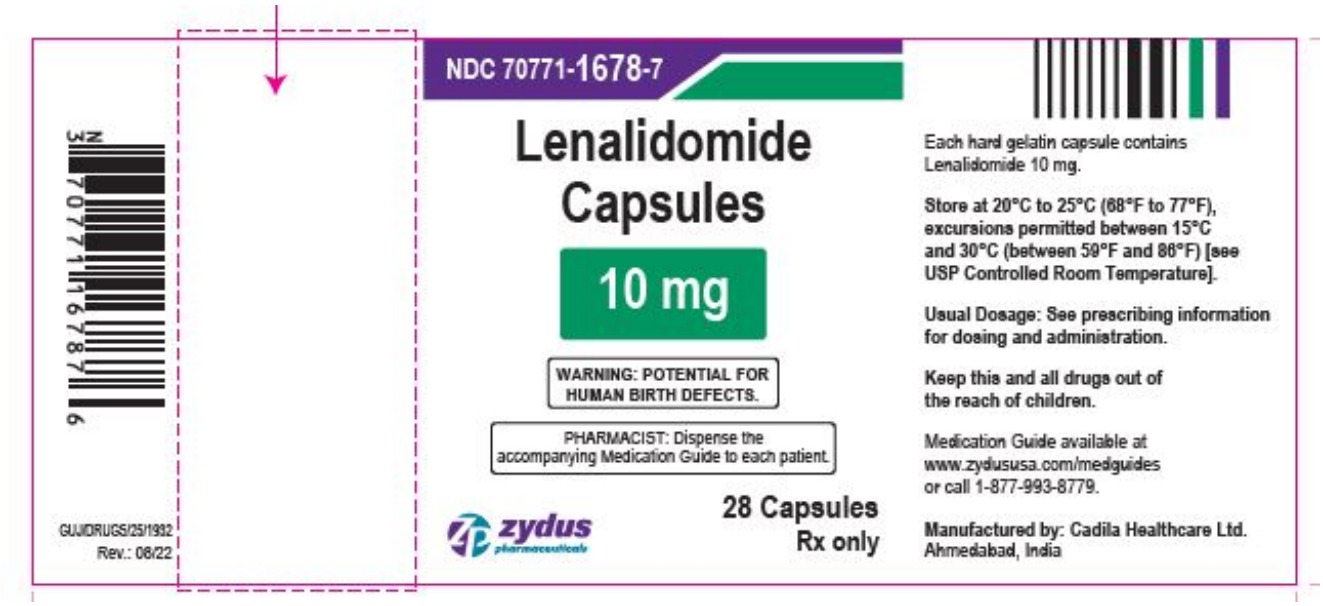
Rx only

NDC 70771-1678-7

Lenalidomide Capsules, 10 mg

28 Capsules

Rx only

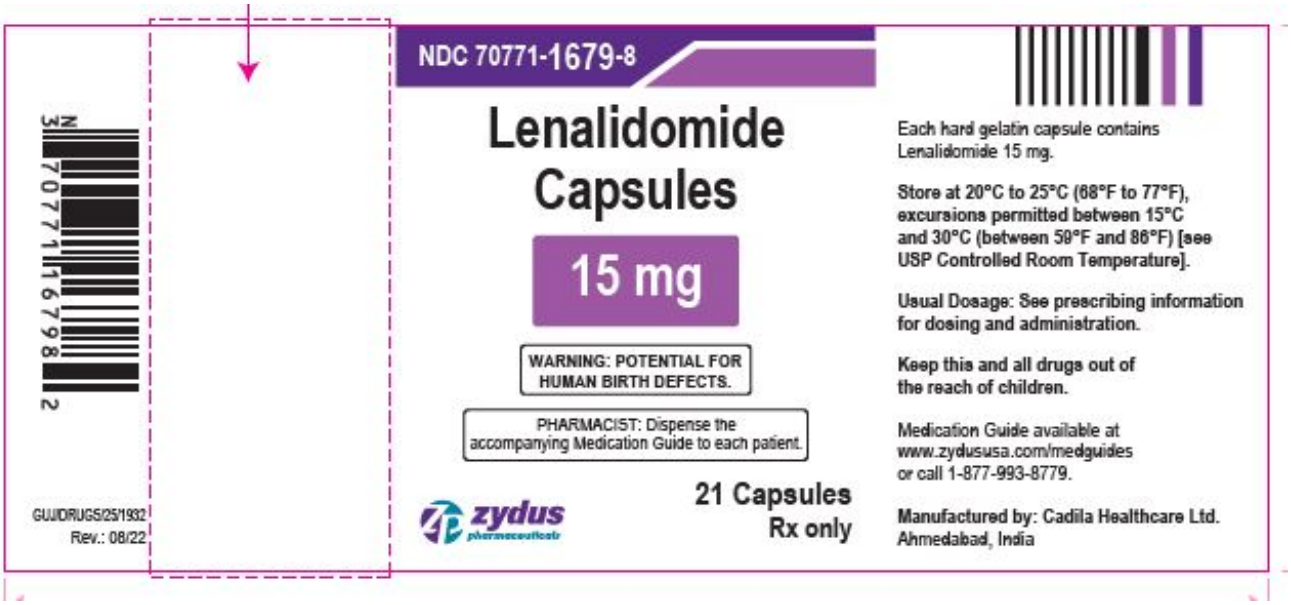


NDC 70771-1679-8

Lenalidomide Capsules, 15 mg

21 Capsules

Rx only

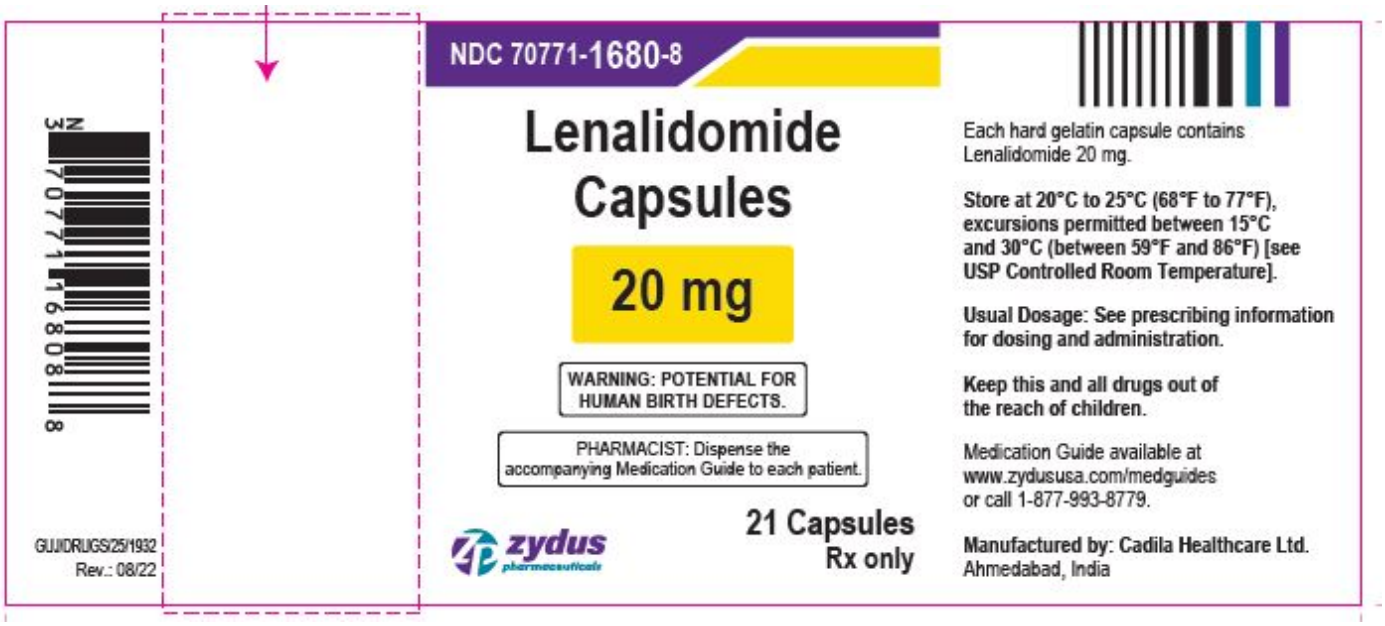


NDC 70771-1680-8

Lenalidomide Capsules, 20 mg

21 Capsules

Rx only



NDC 70771-1681-8

Lenalidomide Capsules, 25 mg

21 Capsules

Rx only

LENALIDOMIDE

lenalidomide capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1677
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LENALIDOMIDE (UNII: F0P408N6V4) (LENALIDOMIDE - UNII:F0P408N6V4)	LENALIDOMIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (white opaque cap with white opaque body)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	11mm

Flavor		**Imprint Code**	1031
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1677-7	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	
2	NDC:70771-1677-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210154	09/12/2022	

LENALIDOMIDE

lenalidomide capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1678
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LENALIDOMIDE (UNII: F0P408N6V4) (LENALIDOMIDE - UNII:F0P408N6V4)	LENALIDOMIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White opaque cap) , BLUE (Turquoise blue opaque body)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	16mm
Flavor		**Imprint Code**	1032
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1678-7	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	
2	NDC:70771-1678-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210154	09/12/2022	

LENALIDOMIDE

lenalidomide capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1679
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LENALIDOMIDE (UNII: F0P408N6V4) (LENALIDOMIDE - UNII:F0P408N6V4)	LENALIDOMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White opaque cap) , BLUE (Light Blue opaque body)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	18mm
Flavor		**Imprint Code**	1033
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1679-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	
2	NDC:70771-1679-8	21 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210154	09/12/2022	

LENALIDOMIDE

lenalidomide capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1681
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LENALIDOMIDE (UNII: F0P408N6V4) (LENALIDOMIDE - UNII:F0P408N6V4)	LENALIDOMIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White opaque cap) , BLUE (Light Blue opaque body)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	22mm
Flavor		**Imprint Code**	1035
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1681-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	
2	NDC:70771-1681-8	21 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210154	09/12/2022	

LENALIDOMIDE

lenalidomide capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1676
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LENALIDOMIDE (UNII: F0P408N6V4) (LENALIDOMIDE - UNII:F0P408N6V4)	LENALIDOMIDE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (white opaque cap with blue opaque body)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	11mm
Flavor		**Imprint Code**	1030
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1676-7	28 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2023	
2	NDC:70771-1676-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210154	03/07/2023	

LENALIDOMIDE

lenalidomide capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1680
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LENALIDOMIDE (UNII: F0P408N6V4) (LENALIDOMIDE - UNII:F0P408N6V4)	LENALIDOMIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (light blue opaque cap turquoise blue opaque body)	**Score**	no score
Shape	CAPSULE (capsule)	**Size**	19mm
Flavor		**Imprint Code**	1034
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1680-8	21 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2023	
2	NDC:70771-1680-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210154	03/07/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1676, 70771-1677, 70771-1678, 70771-1679, 70771-1680, 70771-1681) , MANUFACTURE(70771-1676, 70771-1677, 70771-1678, 70771-1679, 70771-1680, 70771-1681)