AMLODIPINE BESYLATE- amlodipine besylate tablet
Zydus Lifesciences Limited

AMLODIPINE Besylate Tablets

SPL MEDGUIDE

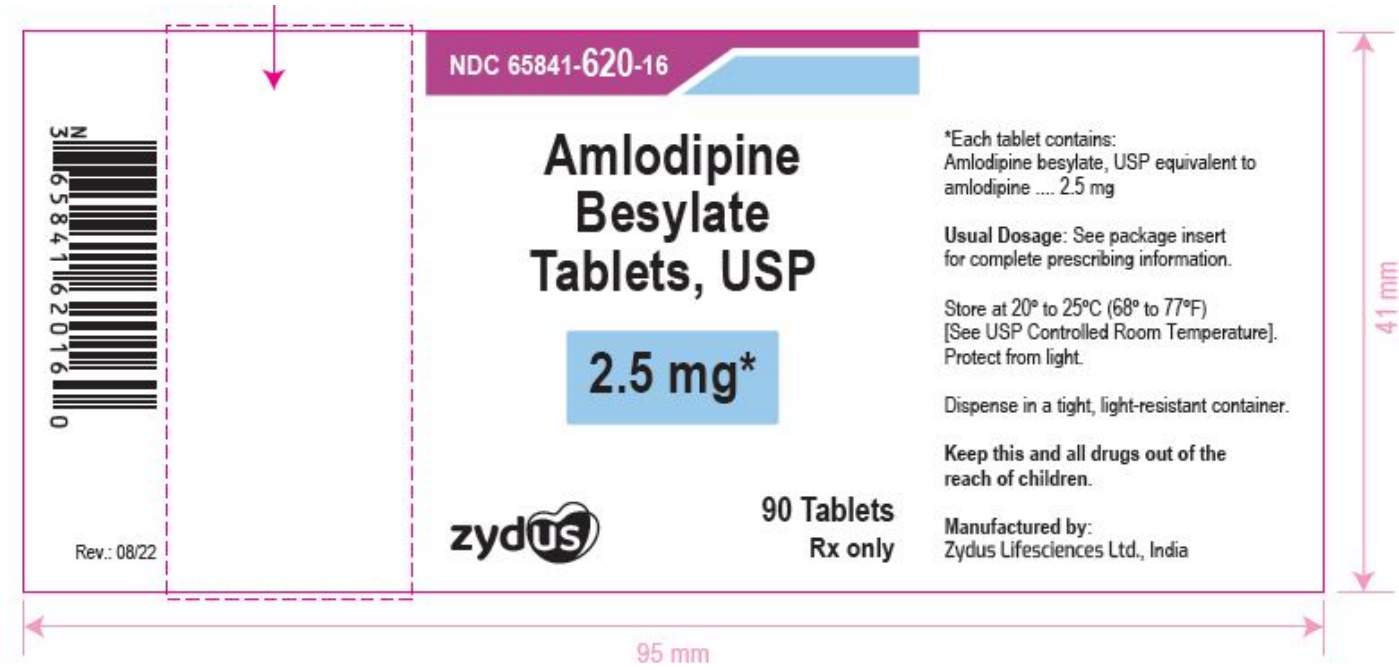
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-620-16 in bottle of 90 tablets

Amlodipine Besylate Tablets USP, 2.5 mg

Rx only

90 tablets



NDC 65841-621-16 in bottle of 90 tablets

Amlodipine Besylate Tablets USP, 5 mg

Rx only

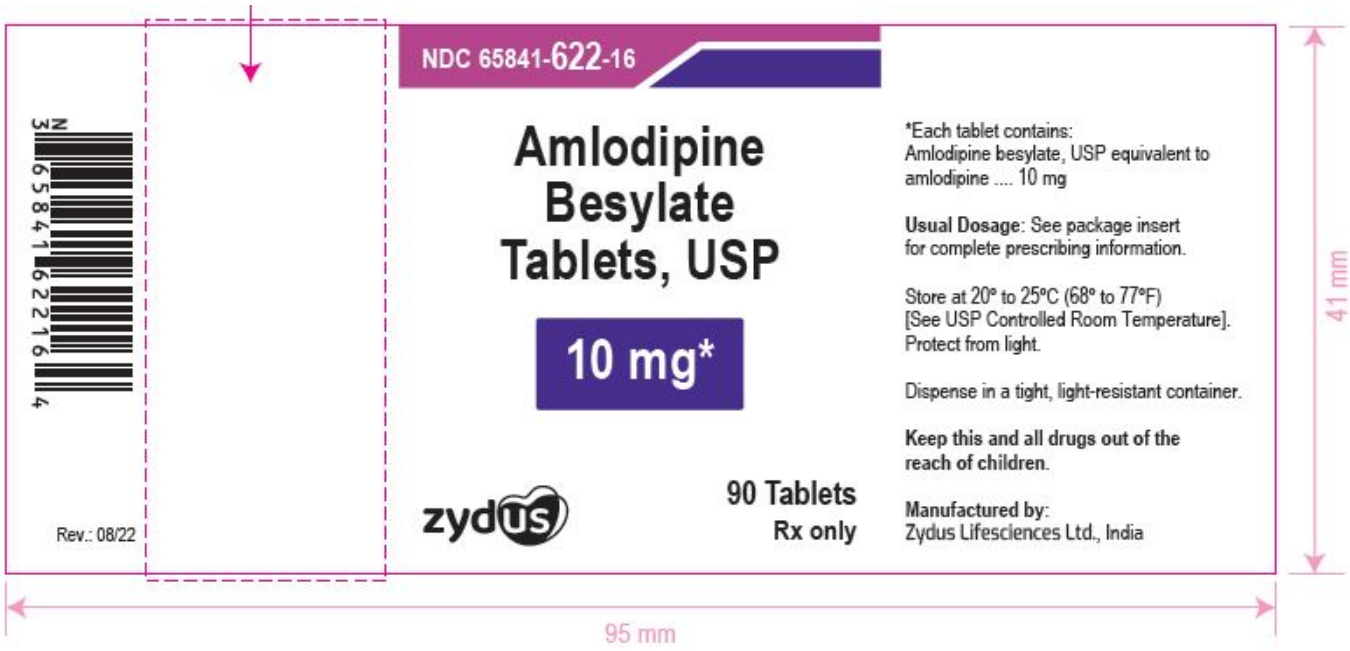
90 tablets

NDC 65841-622-16 in bottle of 90 tablets

Amlodipine Besylate Tablets USP, 10 mg

Rx only

90 tablets



AMLODIPINE BESYLATE

amlodipine besylate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-620
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	4mm
Flavor		**Imprint Code**	Z;7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-620-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
2	NDC:65841-620-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
3	NDC:65841-620-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
4	NDC:65841-620-77	10 in 1 CARTON	09/21/2007	
4		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	ANDA078226	09/21/2007	

AMLODIPINE BESYLATE

amlodipine besylate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-621
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	Z;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-621-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
2	NDC:65841-621-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
3	NDC:65841-621-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
4	NDC:65841-621-77	10 in 1 CARTON	09/21/2007	
4		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	ANDA078226	09/21/2007	

AMLODIPINE BESYLATE

amlodipine besylate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-622
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288)	AMLODIPINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	Z;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-622-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
2	NDC:65841-622-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
3	NDC:65841-622-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/21/2007	
4	NDC:65841-622-77	10 in 1 CARTON	09/21/2007	
4		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	ANDA078226	09/21/2007	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(65841-620, 65841-621, 65841-622) , MANUFACTURE(65841-620, 65841-621, 65841-622)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-620, 65841-621, 65841-622) , MANUFACTURE(65841-620, 65841-621, 65841-622)

Revised: 9/2023 Zydus Lifesciences Limited