

AMLODIPINE BESYLATE- amlodipine besylate tablet
Zydus Lifesciences Limited

AMLODIPINE Besylate Tablets

SPL MEDGUIDE

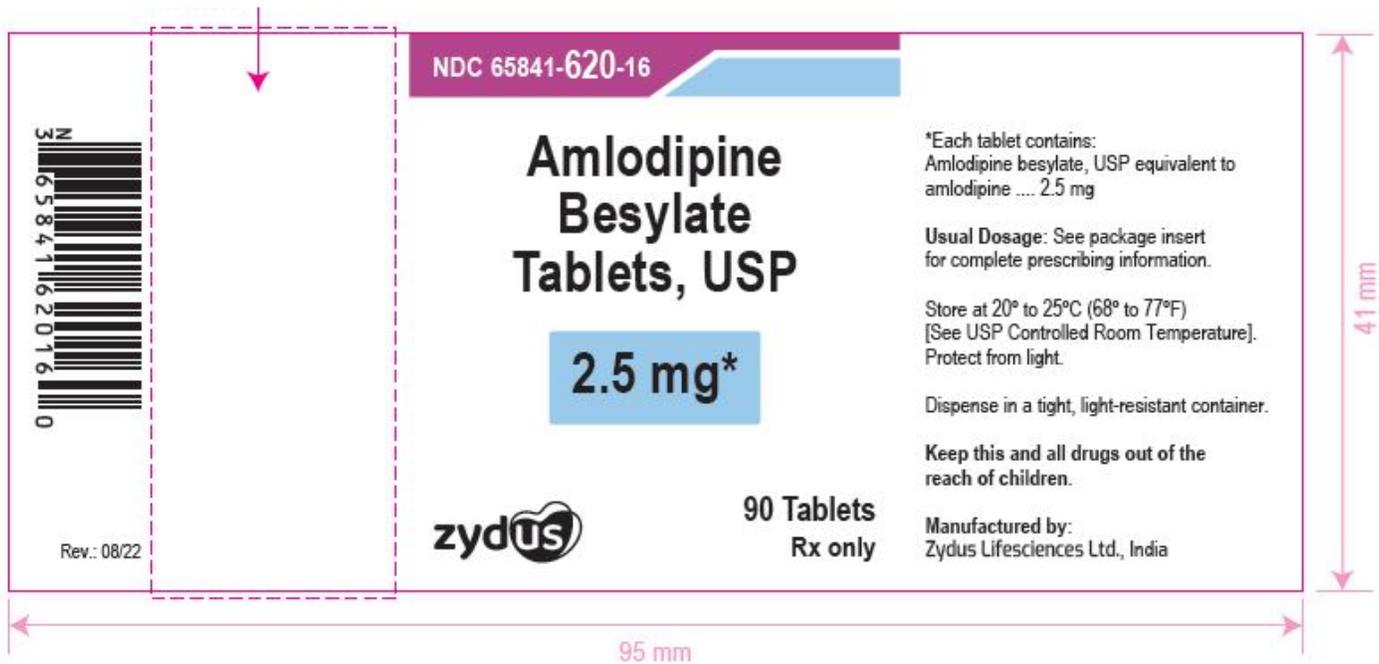
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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: 11/2024

Zydus Lifesciences Limited