

**AMLODIPINE BESYLATE- amlodipine besylate tablet**  
**Cadila Healthcare Limited**

**AMLODIPINE Besylate Tablets**

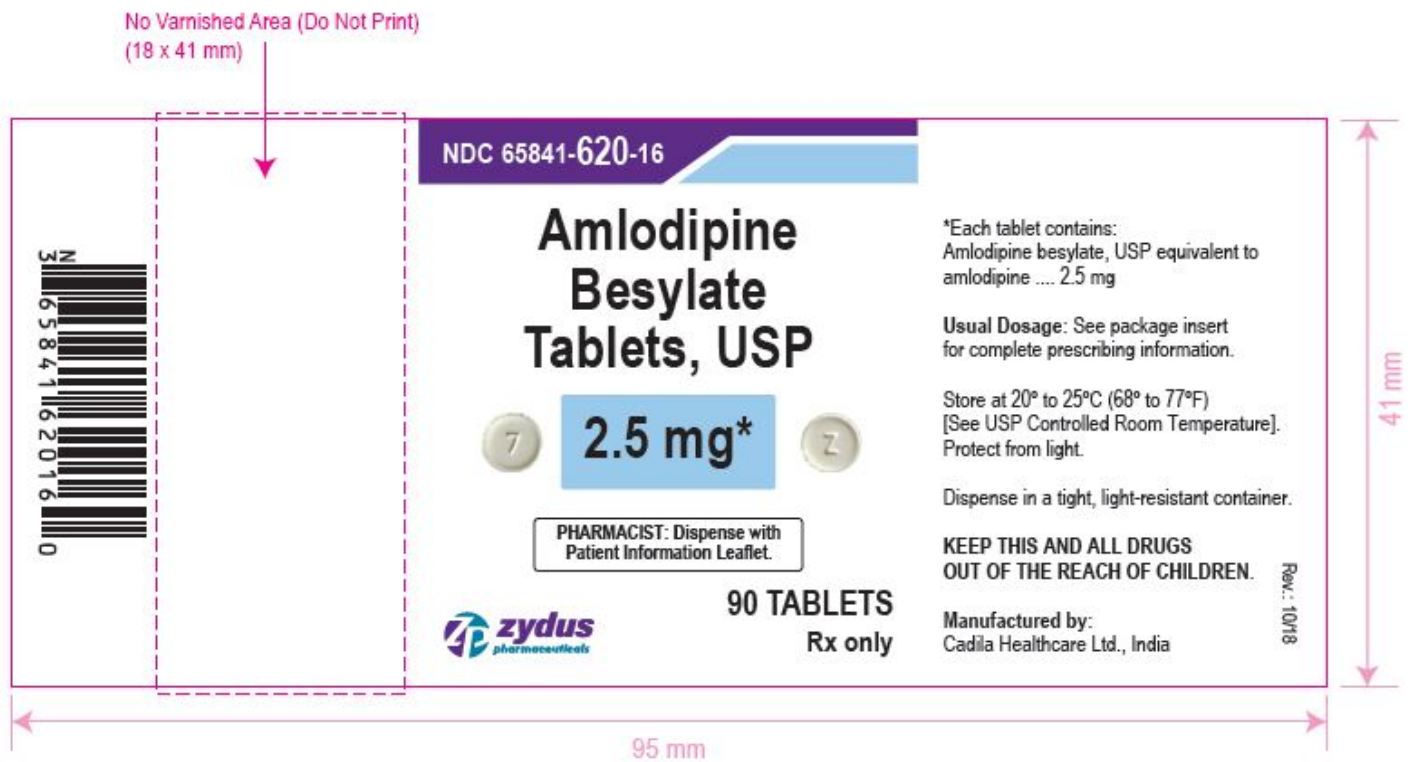
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

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 tablet

### Product Information

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:65841-620 |
| <b>Route of Administration</b> | ORAL                    |                           |               |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| AMLODIPINE BESYLATE (UNII: 864V2Q084H) (AMLODIPINE - UNII:1J444QC288) | AMLODIPINE               | 2.5 mg          |

### Inactive Ingredients

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

### Product Characteristics

|                 |                            |                     |          |
|-----------------|----------------------------|---------------------|----------|
| <b>Color</b>    | WHITE (WHITE TO OFF-WHITE) | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND (ROUND)              | <b>Size</b>         | 4mm      |
| <b>Flavor</b>   |                            | <b>Imprint Code</b> | Z;7      |
| <b>Contains</b> |                            |                     |          |

### 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

|                           |   |                             |                           |
|---------------------------|---|-----------------------------|---------------------------|
| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| ANDA                      | ANDA078226                                      | 09/21/2007                  |                           |

## AMLODIPINE BESYLATE

amlodipine besylate tablet

### Product Information

|                     |                         |                           |               |
|---------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b> | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:65841-621 |
|---------------------|-------------------------|---------------------------|---------------|

|                                |      |
|--------------------------------|------|
| <b>Route of Administration</b> | 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

|                 |                            |                     |          |
|-----------------|----------------------------|---------------------|----------|
| <b>Color</b>    | WHITE (WHITE TO OFF-WHITE) | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND (ROUND)              | <b>Size</b>         | 6 mm     |
| <b>Flavor</b>   |                            | <b>Imprint Code</b> | Z;3      |
| <b>Contains</b> |                            |                     |          |

### 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

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:65841-622 |
| <b>Route of Administration</b> | 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         | 8 mm     |
| 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** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

### Establishment

| Name                      | Address | ID/FEI    | Business Operations  |
|---------------------------|---------|-----------|--|
| CADILA HEALTHCARE LIMITED |         | 677605858 | ANALYSIS(65841-620, 65841-621, 65841-622) , MANUFACTURE(65841-620, 65841-621, 65841-622) |

### Establishment

| Name                      | Address | ID/FEI    | Business Operations  |
|---------------------------|---------|-----------|--|
| Cadila Healthcare Limited |         | 918596198 | ANALYSIS(65841-620, 65841-621, 65841-622) , MANUFACTURE(65841-620, 65841-621, 65841-622) |

