**OMEPRAZOLE- omeprazole capsule, delayed release**
**Zydus Lifesciences Limited**

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**OMEPRAZOLE DELAYED-RELEASE CAPSULES, USP**

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-759-01 in bottle of 100 Capsules

Omeprazole Delayed-release Capsules USP, 10 mg

$R_x$ only

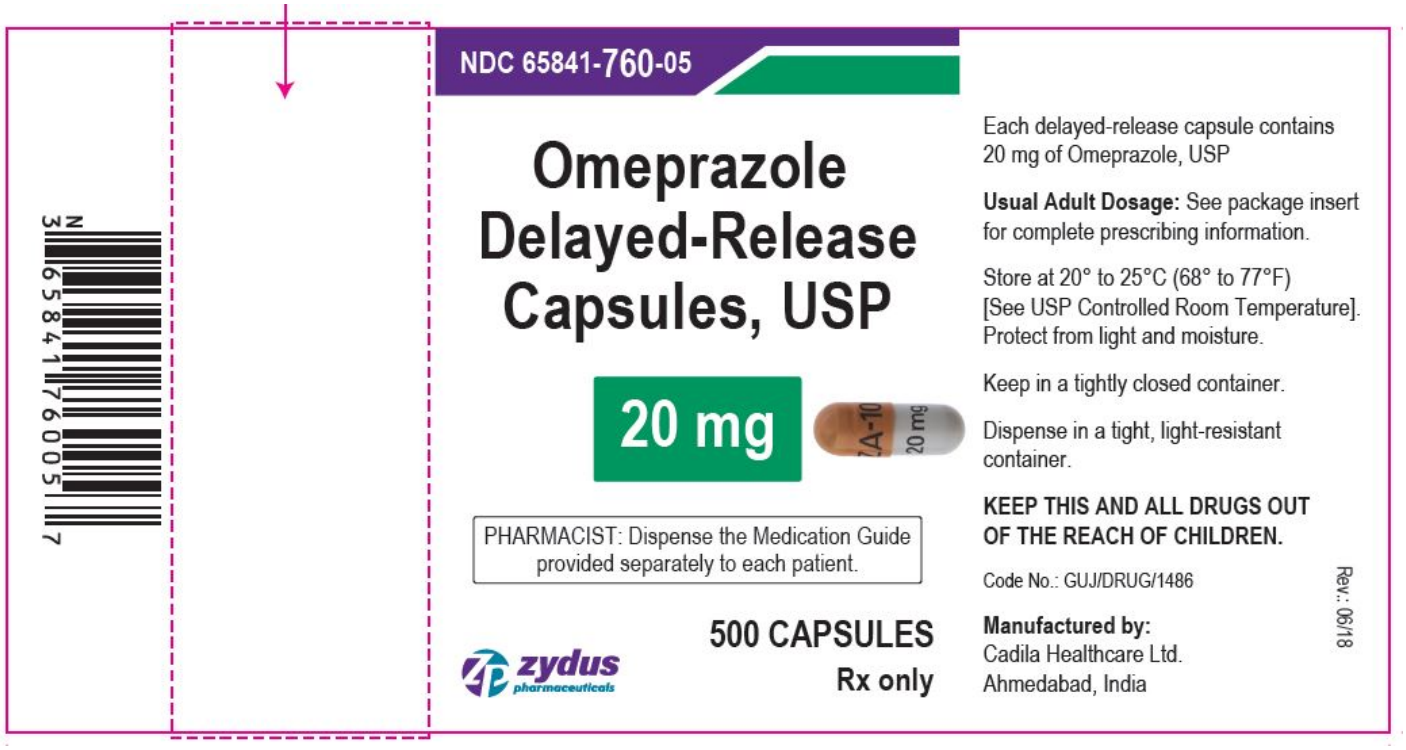
100 Capsules


NDC 65841-760-01 in bottle of 100 Capsules

Omeprazole Delayed-release Capsules USP, 20 mg

$R_x$ only

100 Capsules

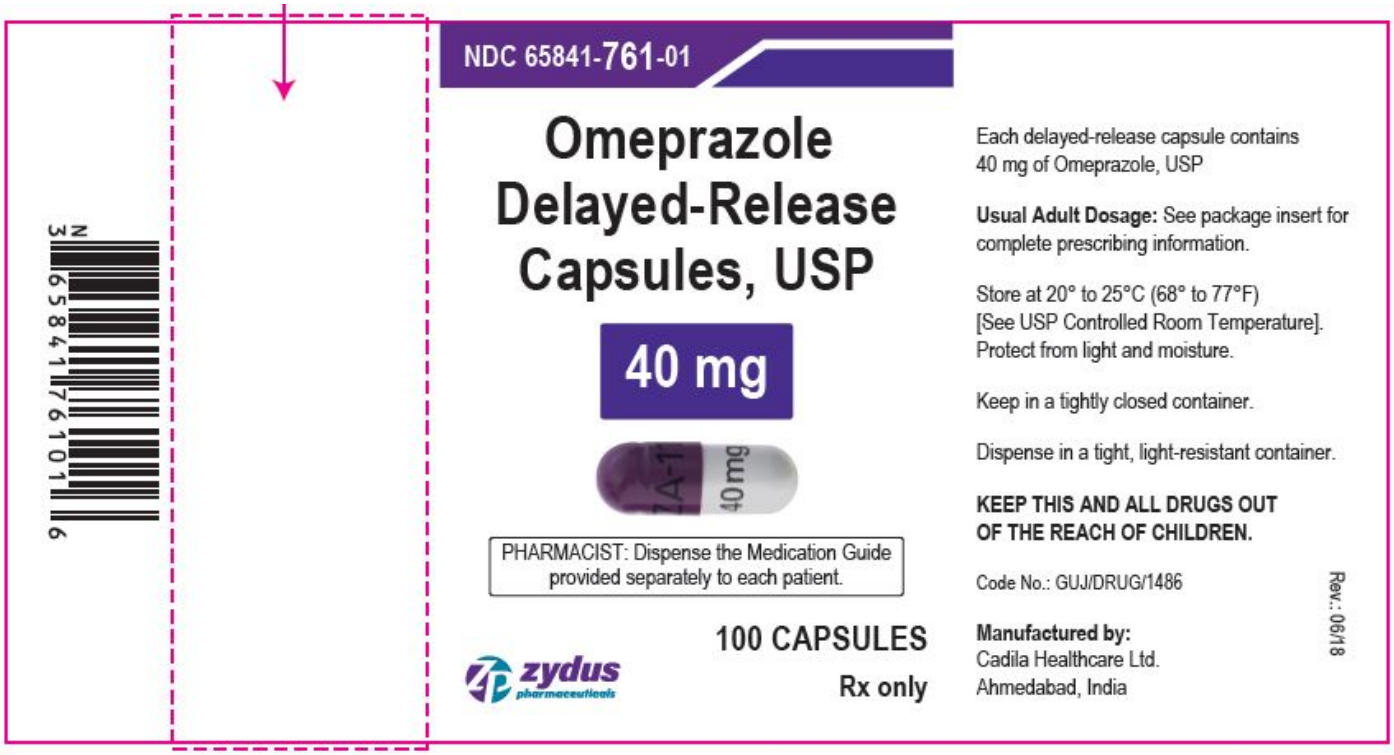



NDC 65841-761-01 in bottle of 100 Capsules

Omeprazole Delayed-release Capsules USP, 40 mg

$R_x$ only

100 Capsules



# OMEPRAZOLE

omeprazole capsule, delayed release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:65841-759 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **OMEPRAZOLE** (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9) | OMEPRAZOLE | 10 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **ACETONE** (UNII: 1364PS73AF) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C GREEN NO. 3** (UNII: 3P3ONR6O1S) | |
| **FD&C RED NO. 3** (UNII: PN2ZH5LOQY) | |
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYDROXYPROPYL CELLULOSE (1600000 WAMW)** (UNII: RFW2ET671P) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST)** (UNII: 8LDD2V82F5) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POTASSIUM HYDROXIDE** (UNII: WZH3C48M4T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **SODIUM PHOSPHATE, DIBASIC, DIHYDRATE** (UNII: 94255I6E2T) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | PURPLE (AMETHYST PURPLE) , WHITE (WHITE) | **Score** | no score |
| **Shape** | CAPSULE (CAPSULE) | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | ZA;09;10mg |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:65841-759-06 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |

| | | | | |
|---|---|---|---|---|
| **2** | NDC:65841-759-16 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **3** | NDC:65841-759-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **4** | NDC:65841-759-05 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **5** | NDC:65841-759-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA091352 | 11/23/2012 | |

# OMEPRAZOLE

omeprazole capsule, delayed release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:65841-760 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OMEPRAZOLE** (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9) | OMEPRAZOLE | 20 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ACETONE** (UNII: 1364PS73AF) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYDROXYPROPYL CELLULOSE (1600000 WAMW)** (UNII: RFW2ET671P) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST)** (UNII: 8LDD2V82F5) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POTASSIUM HYDROXIDE** (UNII: WZH3C48M4T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **SODIUM PHOSPHATE, DIBASIC, DIHYDRATE** (UNII: 94255I6E2T) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| | |
|---|---|
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BROWN (TAN) , WHITE (WHITE) | **Score** | no score |
| **Shape** | CAPSULE (CAPSULE) | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | ZA;10;20mg |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:65841-760-06 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **2** | NDC:65841-760-16 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **3** | NDC:65841-760-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **4** | NDC:65841-760-05 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **5** | NDC:65841-760-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA091352 | 11/23/2012 | |

# OMEPRAZOLE

omeprazole capsule, delayed release

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:65841-761 |
| **Route of Administration** | ORAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OMEPRAZOLE** (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9) | OMEPRAZOLE | 40 mg |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ACETONE** (UNII: 1364PS73AF) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

| | |
|---|---|
| **FD&C GREEN NO. 3** (UNII: 3P3ONR6O1S) | |
| **FD&C RED NO. 3** (UNII: PN2ZH5LOQY) | |
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYDROXYPROPYL CELLULOSE (1600000 WAMW)** (UNII: RFW2ET671P) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST)** (UNII: 8LDD2V82F5) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POTASSIUM HYDROXIDE** (UNII: WZH3C48M4T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **SODIUM PHOSPHATE, DIBASIC, DIHYDRATE** (UNII: 94255I6E2T) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | PURPLE (AMETHYST PURPLE) , WHITE (WHITE) | **Score** | no score |
| **Shape** | CAPSULE (CAPSULE) | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | ZA;11;40mg |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:65841-761-06 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **2** | NDC:65841-761-16 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **3** | NDC:65841-761-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **4** | NDC:65841-761-05 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |
| **5** | NDC:65841-761-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/23/2012 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA091352 | 11/23/2012 | |

## Labeler - Zydus Lifesciences Limited (918596198)

## Registrant - Zydus Lifesciences Limited (918596198)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Zydus Lifesciences Limited | | 918596198 | ANALYSIS(65841-759, 65841-760, 65841-761) , MANUFACTURE(65841-759, 65841-760, 65841-761) |