**AMITRIPTYLINE HYDROCHLORIDE- amitriptyline hydrochloride tablet, film coated**
**Zydus Lifesciences Limited**

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**Amitriptyline Hydrochloride Tablets, USP**

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1173-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 10 mg

Rx only

100 Tablets


NDC 70771-1174-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 25 mg

Rx only

100 Tablets


NDC 70771-1175-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 50 mg

Rx only

100 Tablets


NDC 70771-1176-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 75 mg

Rx only

100 Tablets


NDC 70771-1177-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 100 mg

Rx only

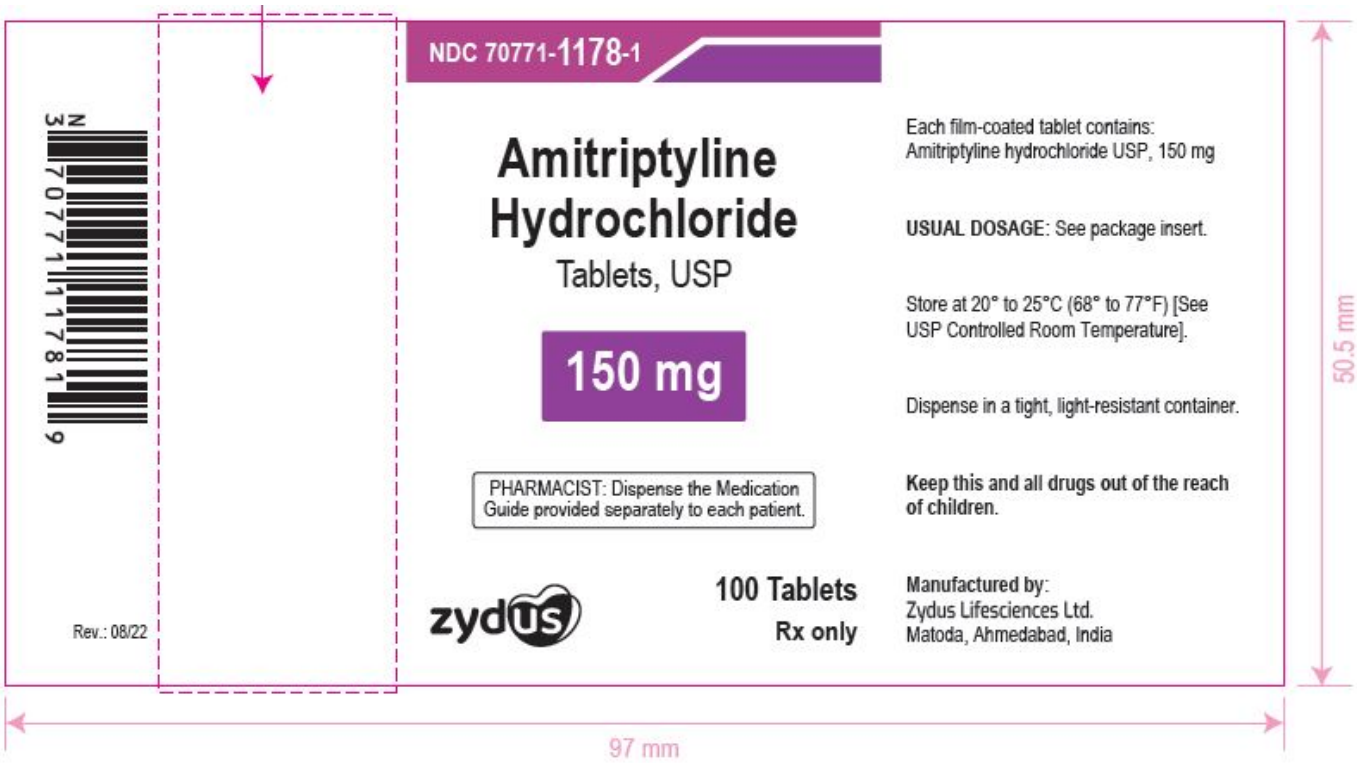
100 Tablets


NDC 70771-1178-1 in bottle of 100 Tablets

Amitriptyline Hydrochloride Tablets USP, 150 mg

Rx only

100 Tablets




# AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1173 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **AMITRIPTYLINE HYDROCHLORIDE** (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K) | AMITRIPTYLINE HYDROCHLORIDE | 10 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |

| | |
|---|---|
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE (OFF-WHITE) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 5mm |
| **Flavor** | | **Imprint Code** | ZA;1 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1173-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |
| **2** | NDC:70771-1173-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA210086 | 12/26/2017 | |

# AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1174 |
| **Route of Administration** | ORAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **AMITRIPTYLINE HYDROCHLORIDE** (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K) | AMITRIPTYLINE HYDROCHLORIDE | 25 mg |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |

| | |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | GREEN (LIGHT GREEN) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 6mm |
| **Flavor** | | **Imprint Code** | ZA;2 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1174-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |
| **2** | NDC:70771-1174-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA210086 | 12/26/2017 | |

# AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1175 |
| **Route of Administration** | ORAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **AMITRIPTYLINE HYDROCHLORIDE** (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K) | AMITRIPTYLINE HYDROCHLORIDE | 50 mg |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BROWN (BROWN) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | ZA;3 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1175-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |
| **2** | NDC:70771-1175-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA210086 | 12/26/2017 | |

# AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1176 |
| **Route of Administration** | ORAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **AMITRIPTYLINE HYDROCHLORIDE** (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K) | AMITRIPTYLINE HYDROCHLORIDE | 75 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BLUE (LIGHT BLUE) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | 12;28 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1176-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |
| **2** | NDC:70771-1176-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA210086 | 12/26/2017 | |

# AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1177 |

| | |
|---|---|
| **Route of Administration** | ORAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **AMITRIPTYLINE HYDROCHLORIDE** (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K) | AMITRIPTYLINE HYDROCHLORIDE | 100 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **D&C RED NO. 27** (UNII: 2LRS185U6K) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | ORANGE (ORANGE) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | 12;29 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1177-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |
| **2** | NDC:70771-1177-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA210086 | 12/26/2017 | |

# AMITRIPTYLINE HYDROCHLORIDE

amitriptyline hydrochloride tablet, film coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1178 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **AMITRIPTYLINE HYDROCHLORIDE** (UNII: 26LUD4JO9K) (AMITRIPTYLINE - UNII:1806D8D52K) | AMITRIPTYLINE HYDROCHLORIDE | 150 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE (CREAM TO BEIGE) | **Score** | no score |
| **Shape** | CAPSULE (MODIFIED CAPSULE) | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | 1230 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1178-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |
| **2** | NDC:70771-1178-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 12/26/2017 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|

| | | | |
|---|---|---|---|
| ANDA | ANDA210086 | 12/26/2017 | |

## Labeler - Zydus Lifesciences Limited (918596198)

## Registrant - Zydus Lifesciences Limited (918596198)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Zydus Lifesciences Limited | | 863362789 | ANALYSIS(70771-1173, 70771-1174, 70771-1175, 70771-1176, 70771-1177, 70771-1178) , MANUFACTURE(70771-1173, 70771-1174, 70771-1175, 70771-1176, 70771-1177, 70771-1178) |

Revised: 9/2023 Zydus Lifesciences Limited