**DESVENLAFAXINE- desvenlafaxine tablet, extended release**
**Zydus Lifesciences Limited**

---

**DESVENLAFAXINE EXTENDED-RELEASE TABLETS**

**SPL MEDGUIDE**

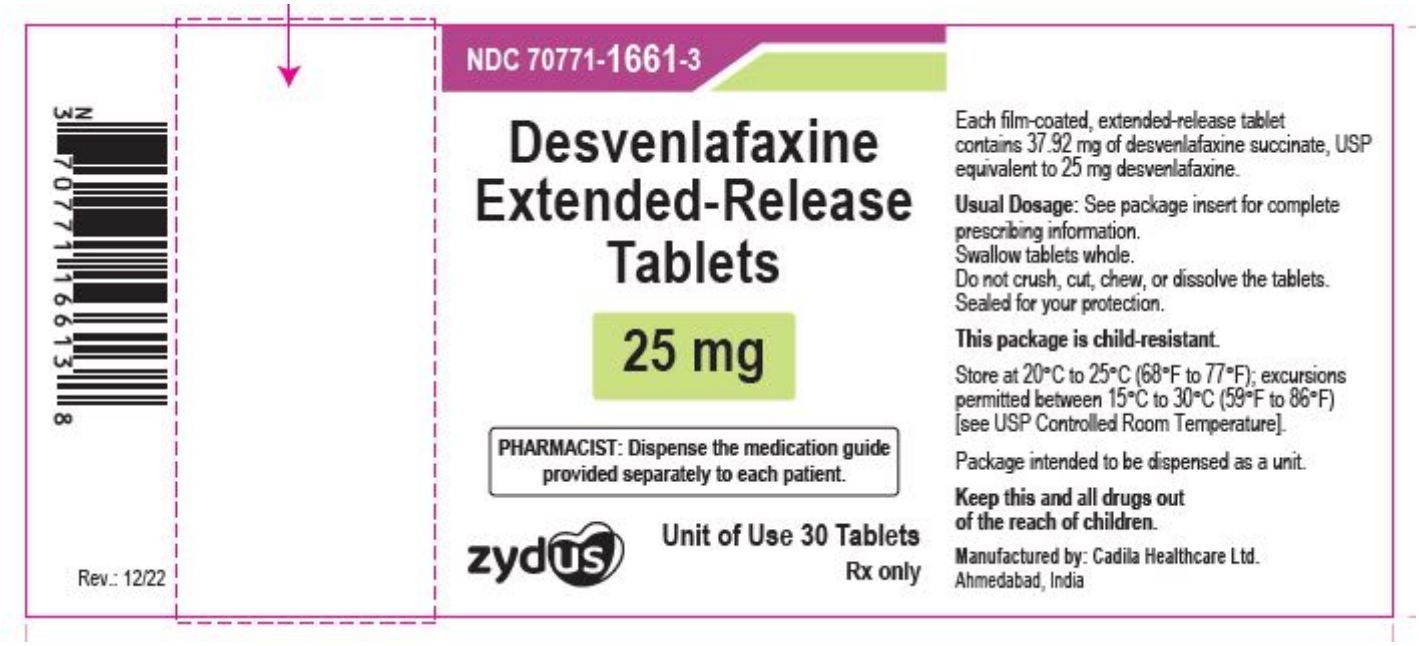
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Desvenlafaxine Extended-release Tablets, 25 mg

NDC 70771-1661-3

30 tablets

Rx only




NDC 68382-469-67 in bottle of 14 tablets in unit-of-use package

Desvenlafaxine Extended-release Tablets, 50 mg

14 tablets

$R_x$ only

Zydus


NDC 68382-741-67 in bottle of 14 tablets in unit-of-use package

Desvenlafaxine Extended-release Tablets, 100 mg

14 tablets

$R_x$ only

Zydus


## DESVENLAFAXINE

desvenlafaxine tablet, extended release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1311 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DESVENLAFAXINE** (UNII: NG99554ANW) (DESVENLAFAXINE - UNII:NG99554ANW) | DESVENLAFAXINE | 50 mg |

| Inactive Ingredients |
|---|

| Ingredient Name | Strength |
|---|---|
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE (WHITE TO OFF-WHITE) | **Score** | no score |
| **Shape** | SQUARE (SQUARE) | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | 469 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1311-7 | 14 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **2** | NDC:70771-1311-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **3** | NDC:70771-1311-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **4** | NDC:70771-1311-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **5** | NDC:70771-1311-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **6** | NDC:70771-1311-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **7** | NDC:70771-1311-4 | 10 in 1 CARTON | 05/08/2018 | |
| **7** | NDC:70771-1311-2 | 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 | ANDA204020 | 05/08/2018 | |

# DESVENLAFAXINE

desvenlafaxine tablet, extended release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1312 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DESVENLAFAXINE** (UNII: NG99554ANW) (DESVENLAFAXINE - UNII:NG99554ANW) | DESVENLAFAXINE | 100 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | ORANGE (ORANGE) | **Score** | no score |
| **Shape** | SQUARE (SQUARE) | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | 741 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1312-7 | 14 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **2** | NDC:70771-1312-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **3** | NDC:70771-1312-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **4** | NDC:70771-1312-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **5** | NDC:70771-1312-5 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **6** | NDC:70771-1312-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 05/08/2018 | |
| **7** | NDC:70771-1312-4 | 10 in 1 CARTON | 05/08/2018 | |
| **7** | NDC:70771-1312-2 | 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 | ANDA204020 | 05/08/2018 | |

# DESVENLAFAXINE

desvenlafaxine tablet, extended release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1661 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DESVENLAFAXINE** (UNII: NG99554ANW) (DESVENLAFAXINE - UNII:NG99554ANW) | DESVENLAFAXINE | 25 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **HYPROMELLOSE 2208 (100 MPA.S)** (UNII: B1QE5P712K) | |
| **HYPROMELLOSE 2208 (15000 MPA.S)** (UNII: Z78RG6M2N2) | |
| **HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE 102** (UNII: PNR0YF693Y) | |
| **POLYETHYLENE GLYCOL 4000** (UNII: 4R4HFI6D95) | |
| **POLYETHYLENE GLYCOL 6000** (UNII: 30IQX730WE) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | YELLOW (Light Yellow to Yellow) | **Score** | no score |
| **Shape** | SQUARE (Square) | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | 1257 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start | Marketing End |
|---|---|---|---|---|

| # | Item Code | Package Description | Date | Date |
|---|---|---|---|---|
| 1 | NDC:70771-1661-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/30/2022 | |
| 2 | NDC:70771-1661-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/30/2022 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA204020 | 11/30/2022 | |

## Labeler - Zydus Lifesciences Limited (918596198)

## Registrant - Zydus Lifesciences Limited (918596198)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Zydus Lifesciences Limited | | 918596198 | ANALYSIS(70771-1311, 70771-1312, 70771-1661) , MANUFACTURE(70771-1311, 70771-1312, 70771-1661) |

Revised: 9/2023 Zydus Lifesciences Limited