**VARDENAFIL- vardenafil tablet, film coated**
**Zydus Lifesciences Limited**

---

**VARDENAFIL HYDROCHLORIDE TABLETS**

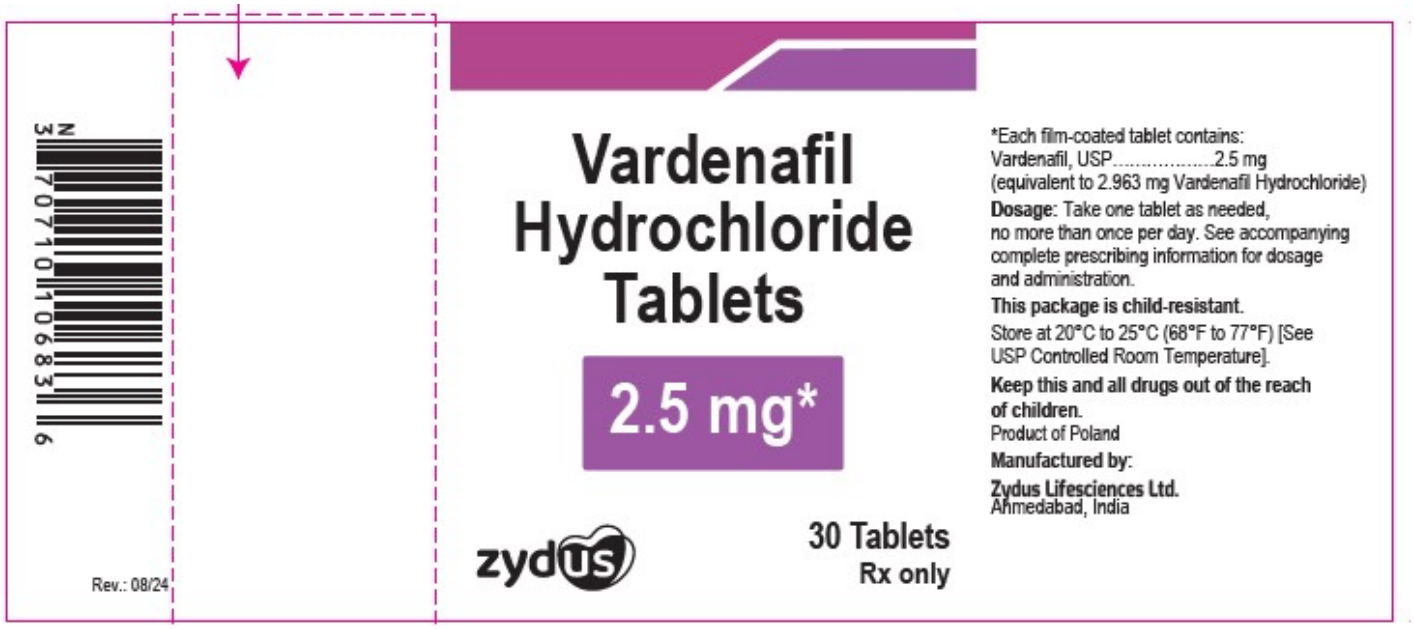
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1047-3

Vardenafil Tablets, 2.5 mg

30 Tablets

Rx only




NDC 70771-1048-3

Vardenafil Tablets, 5 mg

30 Tablets

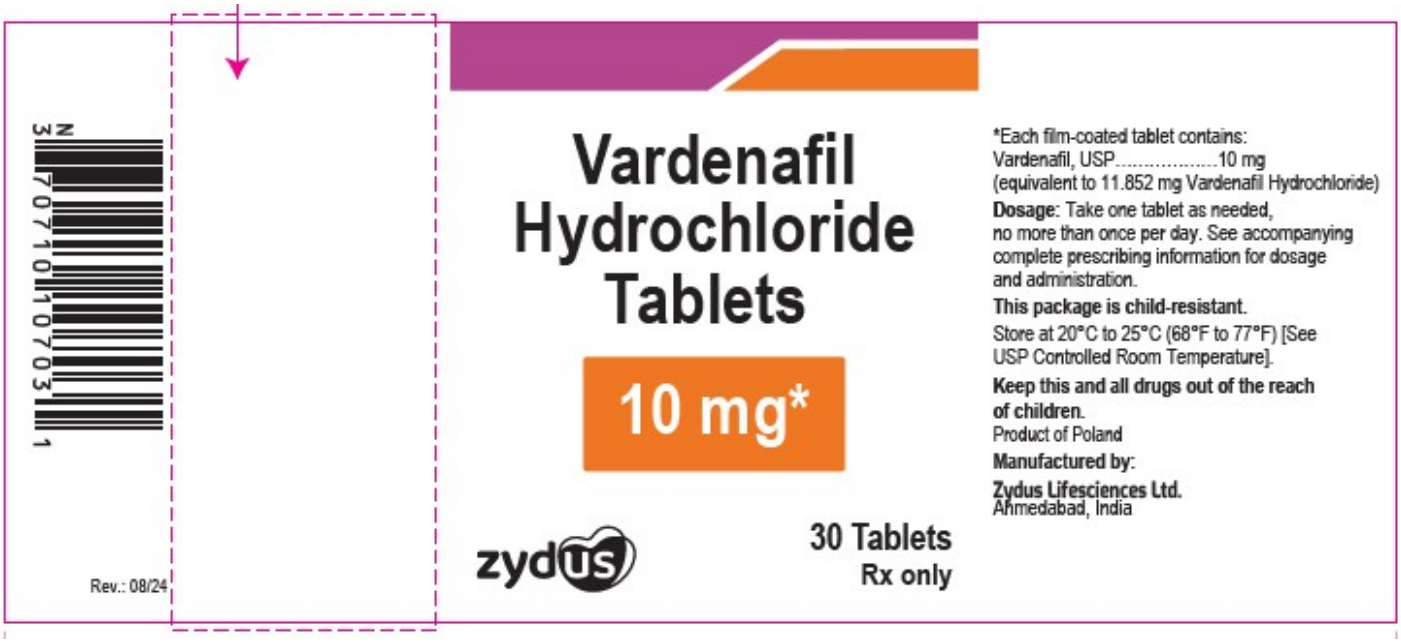
Rx only


NDC 70771-1049-3

Vardenafil Tablets, 10 mg

30 Tablets

Rx only

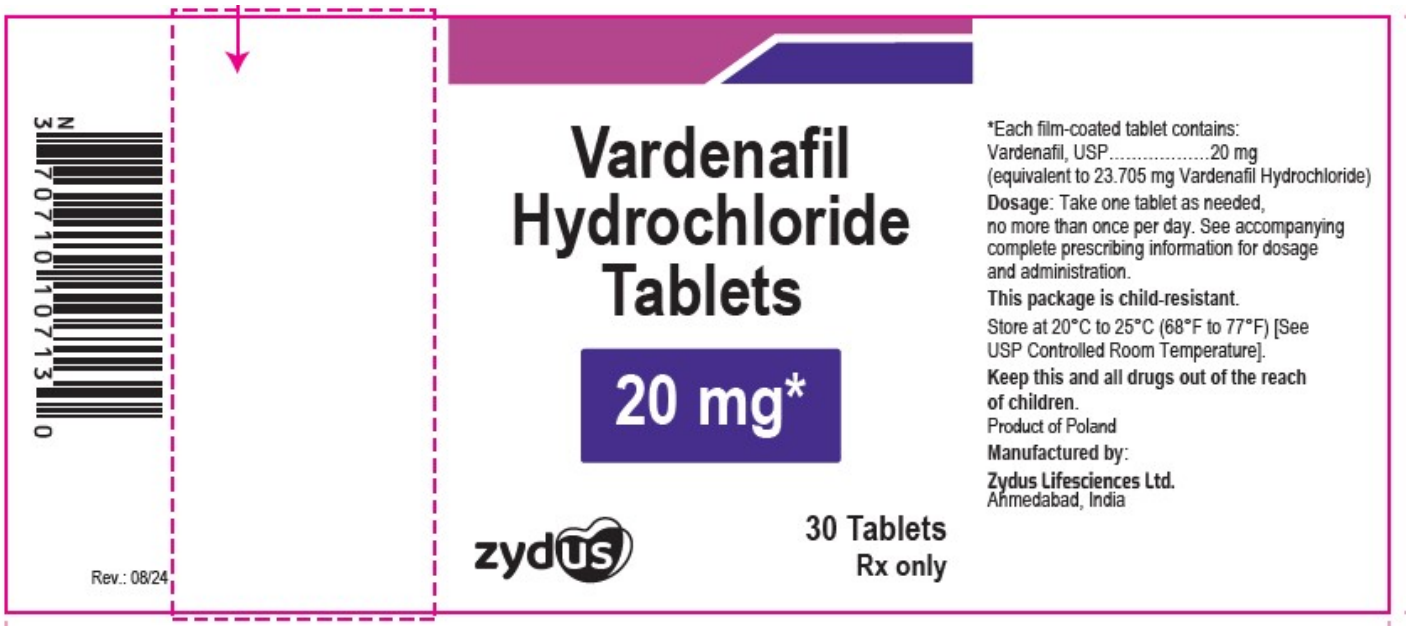



NDC 70771-1050-3

Vardenafil Tablets, 20 mg

30 Tablets

Rx only




# VARDENAFIL

vardenafil tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1047 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **VARDENAFIL HYDROCHLORIDE TRIHYDRATE** (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H) | VARDENAFIL | 2.5 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STEARYL FUMARATE** (UNII: 7CV7WJK4UI) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE (WHITE TO OFF-WHITE) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 5mm |
| **Flavor** | | **Imprint Code** | 10;68 |

| Contains | |
|---|---|

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:70771-1047-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| 2 | NDC:70771-1047-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| 3 | NDC:70771-1047-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA208960 | 11/01/2018 | |

# VARDENAFIL

vardenafil tablet, film coated

### Product Information

| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1048 |
|---|---|---|---|
| Route of Administration | ORAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **VARDENAFIL HYDROCHLORIDE TRIHYDRATE** (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H) | VARDENAFIL | 5 mg |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STEARYL FUMARATE** (UNII: 7CV7WJK4UI) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | YELLOW (LIGHT YELLOW) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 5mm |
| **Flavor** | | **Imprint Code** | 10;69 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:70771-1048-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| **2** | NDC:70771-1048-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| **3** | NDC:70771-1048-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA208960 | 11/01/2018 | |

# VARDENAFIL

vardenafil tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1049 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **VARDENAFIL HYDROCHLORIDE TRIHYDRATE** (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H) | VARDENAFIL | 10 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STEARYL FUMARATE** (UNII: 7CV7WJK4UI) | |

| | |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | YELLOW (LIGHT YELLOW TO ORANGE) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 7mm |
| **Flavor** | | **Imprint Code** | 10;70 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1049-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| **2** | NDC:70771-1049-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| **3** | NDC:70771-1049-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA208960 | 11/01/2018 | |

# VARDENAFIL

vardenafil tablet, film coated

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:70771-1050 |
| **Route of Administration** | ORAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **VARDENAFIL HYDROCHLORIDE TRIHYDRATE** (UNII: 5M8S2CU0TS) (VARDENAFIL - UNII:UCE6F4125H) | VARDENAFIL | 20 mg |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

| | |
|---|---|
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STEARYL FUMARATE** (UNII: 7CV7WJK4UI) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | YELLOW (LIGHT YELLOW TO ORANGE) | **Score** | no score |
| **Shape** | ROUND (ROUND) | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | 10;71 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70771-1050-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| **2** | NDC:70771-1050-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |
| **3** | NDC:70771-1050-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA208960 | 11/01/2018 | |

## Labeler - Zydus Lifesciences Limited (918596198)

## Registrant - Zydus Lifesciences Limited (863362789)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Zydus Lifesciences Limited | | 863362789 | ANALYSIS(70771-1047, 70771-1048, 70771-1049, 70771-1050) , MANUFACTURE(70771-1047, 70771-1048, 70771-1049, 70771-1050) |

Revised: 8/2024 Zydus Lifesciences Limited