

VARDENAFIL- vardenafil tablet, film coated
Zydus Lifesciences Limited

VARDENAFIL TABLETS USP, for oral use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1047-3

Vardenafil Tablets USP, 2.5 mg

30 Tablets

Rx only

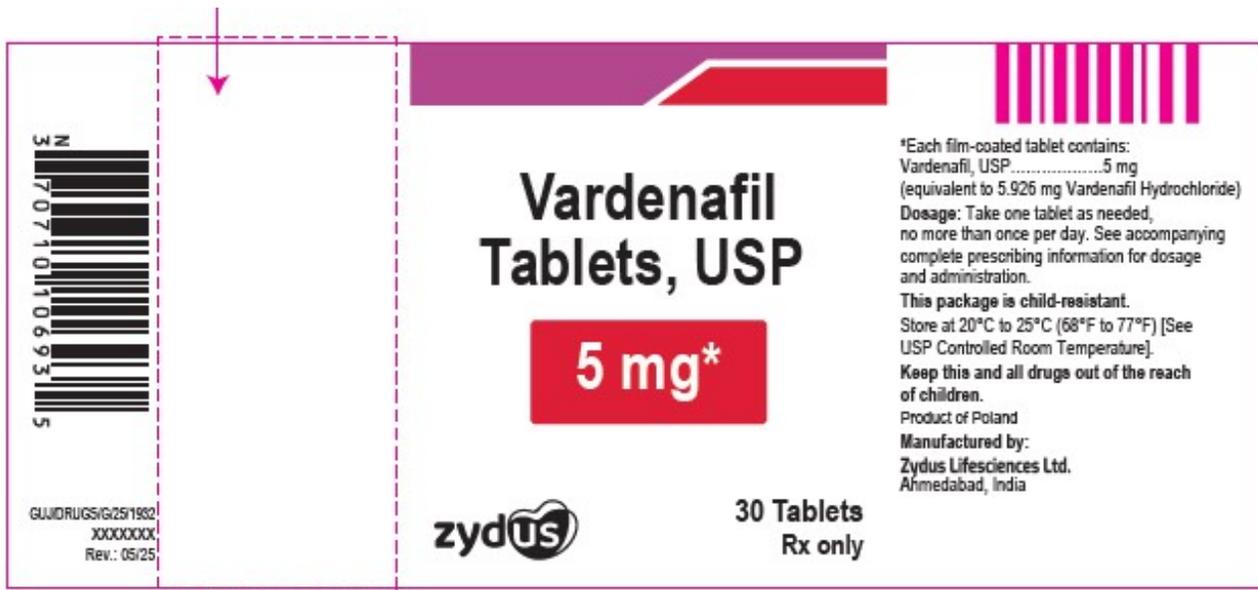


NDC 70771-1048-3

Vardenafil Tablets USP, 5 mg

30 Tablets

Rx only



NDC 70771-1049-3

Vardenafil Tablets USP, 10 mg

30 Tablets

Rx only



NDC 70771-1050-3

Vardenafil Tablets USP, 20 mg

30 Tablets

Rx only

Vardenafil Tablets, USP

20 mg*

zydus

30 Tablets Rx only

*Each film-coated tablet contains: Vardenafil, USP20 mg (equivalent to 23.705 mg Vardenafil Hydrochloride)
 Dosage: Take one tablet as needed, no more than once per day. See accompanying complete prescribing information for dosage and administration.
 This package is child-resistant.
 Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
 Keep this and all drugs out of the reach of children.
 Product of Poland
 Manufactured by:
 Zydus Lifesciences Ltd.
 Ahmedabad, India

GUJDRUGS/G/25/1932
 XXXXXXXX
 Rev.: 05/25

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: 3WJQ0SDW1A) | |
| 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: 3WJQ0SDW1A) | |
| 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: 3WJQ0SDW1A) | |
| 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: 3WJQ0SDW1A) | |
| 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: 1/2026

Zydus Lifesciences Limited