

**VARENICLINE- varenicline tablet, film coated**  
**Zydus Lifesciences Limited**

**Varenicline Tablets**

**SPL MEDGUIDE**

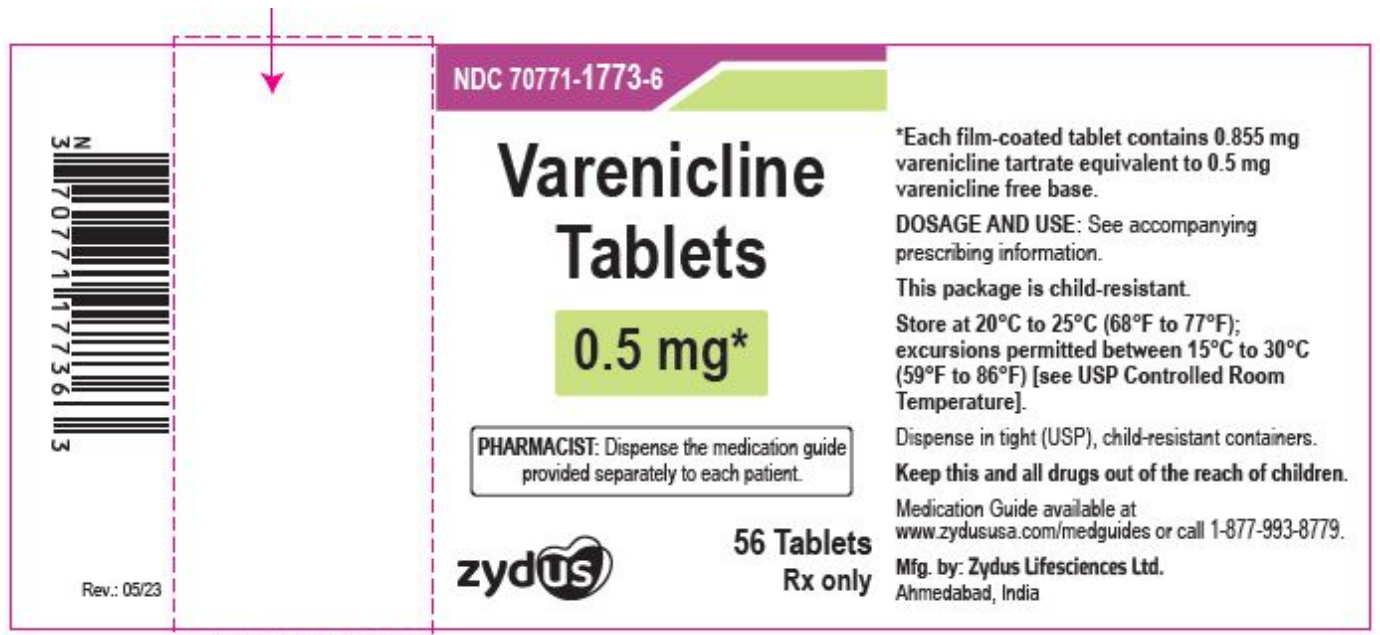
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1773-6

Varenicline Tablets, 0.5 mg

56 Tablets

Rx only

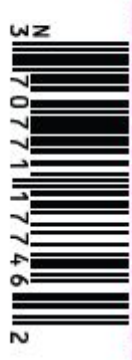


NDC 70771-1774-6

Varenicline Tablets, 1 mg

56 Tablets

Rx only



Rev.: 05/23

NDC 70771-1774-6

## Varenicline Tablets

1 mg\*

**PHARMACIST:** Dispense the medication guide  
provided separately to each patient.



**56 Tablets**  
**Rx only**

\*Each film-coated tablet contains 1.71 mg varenicline tartrate equivalent to 1 mg varenicline free base.

**DOSAGE AND USE:** See accompanying prescribing information.

This package is child-resistant.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Dispense in tight (USP), child-resistant containers.

**Keep this and all drugs out of the reach of children.**

Medication Guide available at [www.zydususa.com/medguides](http://www.zydususa.com/medguides) or call 1-877-993-8779.

Mfg. by: Zydus Lifesciences Ltd.  
Ahmedabad, India

## VARENICLINE

varenicline tablet, film coated

### Product Information

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:70771-1773 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name                                                                | Basis of Strength | Strength |
|--------------------------------------------------------------------------------|-------------------|----------|
| <b>VARENICLINE TARTRATE</b> (UNII: 82269ASB48) (VARENICLINE - UNII:W6HS99O8ZO) | VARENICLINE       | 0.5 mg   |

### Inactive Ingredients

| Ingredient Name                                               | Strength |
|---------------------------------------------------------------|----------|
| <b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J) |          |
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)               |          |
| <b>HYPROMELLOSE 2910 (3 MPA.S)</b> (UNII: 0VUT3PMY82)         |          |
| <b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)         |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                  |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)         |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                     |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                    |          |
| <b>TRIACETIN</b> (UNII: XHX3C3X673)                           |          |

### Product Characteristics

|              |                            |              |          |
|--------------|----------------------------|--------------|----------|
| <b>Color</b> | WHITE (WHITE TO OFF-WHITE) | <b>Score</b> | no score |
| <b>Shape</b> | CAPSULE                    | <b>Size</b>  | 8mm      |

|                       |                  |                                                   |                      |                    |
|-----------------------|------------------|---------------------------------------------------|----------------------|--------------------|
| Flavor                |                  | Imprint Code                                      |                      | ZV1                |
| Contains              |                  |                                                   |                      |                    |
|                       |                  |                                                   |                      |                    |
| Packaging             |                  |                                                   |                      |                    |
| #                     | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
| 1                     | NDC:70771-1773-6 | 56 in 1 BOTTLE; Type 0: Not a Combination Product | 06/13/2023           |                    |
|                       |                  |                                                   |                      |                    |
| Marketing Information |                  |                                                   |                      |                    |
| Marketing Category    |                  | Application Number or Monograph Citation          | Marketing Start Date | Marketing End Date |
| ANDA                  |                  | ANDA216723                                        | 06/13/2023           |                    |
|                       |                  |                                                   |                      |                    |

|                                                                         |                           |                    |                |
|-------------------------------------------------------------------------|---------------------------|--------------------|----------------|
| VARENICLINE                                                             |                           |                    |                |
| varenicline tablet, film coated                                         |                           |                    |                |
| Product Information                                                     |                           |                    |                |
| Product Type                                                            | HUMAN PRESCRIPTION DRUG   | Item Code (Source) | NDC:70771-1774 |
| Route of Administration                                                 | ORAL                      |                    |                |
| Active Ingredient/Active Moiety                                         |                           |                    |                |
| Ingredient Name                                                         |                           | Basis of Strength  | Strength       |
| VARENICLINE TARTRATE (UNII: 82269ASB48) (VARENICLINE - UNII:W6HS99O8ZO) |                           | VARENICLINE        | 1 mg           |
| Inactive Ingredients                                                    |                           |                    |                |
| Ingredient Name                                                         |                           |                    | Strength       |
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)                  |                           |                    |                |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)                                |                           |                    |                |
| HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)                          |                           |                    |                |
| HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)                          |                           |                    |                |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                                   |                           |                    |                |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)                          |                           |                    |                |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                                      |                           |                    |                |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                                     |                           |                    |                |
| TRIACETIN (UNII: XHX3C3X673)                                            |                           |                    |                |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)                        |                           |                    |                |
| Product Characteristics                                                 |                           |                    |                |
| Color                                                                   | BLUE (Light Blue to Blue) | Score              | no score       |
| Shape                                                                   | CAPSULE                   | Size               | 10mm           |

|                              |                                                 |                                                   |                             |
|------------------------------|-------------------------------------------------|---------------------------------------------------|-----------------------------|
| <b>Flavor</b>                |                                                 | <b>Imprint Code</b>                               | ZV2                         |
| <b>Contains</b>              |                                                 |                                                   |                             |
|                              |                                                 |                                                   |                             |
| <b>Packaging</b>             |                                                 |                                                   |                             |
| <b>#</b>                     | <b>Item Code</b>                                | <b>Package Description</b>                        | <b>Marketing Start Date</b> |
| <b>Marketing End Date</b>    |                                                 |                                                   |                             |
| 1                            | NDC:70771-1774-6                                | 56 in 1 BOTTLE; Type 0: Not a Combination Product | 06/13/2023                  |
|                              |                                                 |                                                   |                             |
| <b>Marketing Information</b> |                                                 |                                                   |                             |
| <b>Marketing Category</b>    | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b>                       | <b>Marketing End Date</b>   |
| ANDA                         | ANDA216723                                      | 06/13/2023                                        |                             |
|                              |                                                 |                                                   |                             |

**Labeler -** Zydus Lifesciences Limited (918596198)

|                            |                |               |                                                                        |
|----------------------------|----------------|---------------|------------------------------------------------------------------------|
| <b>Establishment</b>       |                |               |                                                                        |
| <b>Name</b>                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>                                             |
| Zydus Lifesciences Limited |                | 863362789     | ANALYSIS(70771-1773, 70771-1774) , MANUFACTURE(70771-1773, 70771-1774) |