

**ITRACONAZOLE - itraconazole capsule**  
**Zydus Lifesciences Limited**

**Itraconazole Capsules, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Itraconazole Capsules, 100 mg  
 NDC 70771-1208-3  
 30 Capsules

**ZyGenerics**  
 NDC 70771-1208-3  
**ITRACONAZOLE**  
 Capsules  
**100 mg**

PHARMACIST: Dispense the Patient Information provided separately to each patient.

**Rx only**  
**30 Capsules**

Each capsule contains 100 mg of itraconazole, USP.  
**Usual Dosage:** See package insert for complete prescribing information.  
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
 Protect from light and moisture.  
 Dispense in a tight, light-resistant container as defined in the USP.  
**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**  
**Manufactured by:**  
 Cadila Healthcare Ltd.  
 Ahmedabad, India

Lot:  
 Exp:  
 Rev: 02/18

**ITRACONAZOLE**

itraconazole capsule

**Product Information**

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:70771-1208 |
| <b>Route of Administration</b> | ORAL                    |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| ITRACONAZOLE (UNII: 304NUG5GF4) (ITRACONAZOLE - UNII:304NUG5GF4) | ITRACONAZOLE      | 100 mg   |

**Inactive Ingredients**

| Ingredient Name                                     | Strength |
|---|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                  |          |
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY)                   |          |
| GELATIN (UNII: 2G86QN327L)                          |          |
| HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)      |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)            |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |

|   |
|---|
| <b>SUCROSE</b> (UNII: C151H8M554)             |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)    |
| <b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)       |
| <b>ALCOHOL</b> (UNII: 3K9958V90M)             |
| <b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)   |
| <b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T) |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)    |
| <b>WATER</b> (UNII: 059QF0K00R)               |
| <b>SHELLAC</b> (UNII: 46N107B71O)             |
| <b>AMMONIA</b> (UNII: 5138Q19F1X)             |
| <b>POLOXAMER 188</b> (UNII: LQA7B6G8JG)       |

### Product Characteristics

|                 |                   |                     |              |
|-----------------|-------------------|---------------------|--------------|
| <b>Color</b>    | BLUE (BLUE)       | <b>Score</b>        | no score     |
| <b>Shape</b>    | CAPSULE (CAPSULE) | <b>Size</b>         | 23mm         |
| <b>Flavor</b>   |                   | <b>Imprint Code</b> | ZA;65;100;mg |
| <b>Contains</b> |                   |                     |              |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1208-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product      | 03/06/2018           |                    |
| 2 | NDC:70771-1208-0 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product     | 03/06/2018           |                    |
| 3 | NDC:70771-1208-4 | 10 in 1 CARTON  | 03/06/2018           |                    |
| 3 | NDC:70771-1208-2 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 4 | NDC:70771-1208-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product       | 03/06/2018           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA204672                               | 03/06/2018           |                    |

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

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

### Establishment

| Name                       | Address | ID/FEI    | Business Operations                            |
|----------------------------|---------|-----------|--|
| Zydus Lifesciences Limited |         | 918596198 | ANALYSIS(70771-1208) , MANUFACTURE(70771-1208) |

