

**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)

