KETOCONAZOLE- ketoconazole shampoo
Zydus Lifesciences Limited

Ketoconazole Shampoo, 2%

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1874-7

Ketoconazole Shampoo, 2%

For Topical Application Only

4 FL OZ (120 mL)

Rx Only

Front Image

Ketoconazole Shampoo, 2 %

For Topical Application Only

Dosage:

One application of the shampoo should be sufficient and then intermittently as needed.

Direction for Use

Apply the shampoo to the damp skin of the affected area and a wide margin surrounding this area. Lather, leave in place for 5 minutes, and then rinse off with water.

Active ingredients: Ketoconazole, USP

Inactive ingredients: cocodiethanolamide, disodium laureth sulfosuccinate, FD&C red no. 40, hydrochloric acid, imidurea, laurdimonium hydroxypropyl hydrolyzed animal collagen, PEG-120 methyl glucose dioleate, purified water, sodium chloride, sodium hydroxide and sodium lauryl ether sulfate.

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

Protect from light.

GUJ/DRUGS/G/25/1919

Rev.: 03/24

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

Mfg. by: Zydus Lifesciences Ltd.
Changodar, Ahmedabad, India

Back image

KETOCONAZOLE

ketoconazole shampoo

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1874
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
IMIDUREA (UNII: M629807ATL)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1874-7	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/08/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218559	03/08/2025	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1874) , MANUFACTURE(70771-1874)

Revised: 3/2025 Zydus Lifesciences Limited