IRISTAR ANTI DANDRUFF SHAMPOO.- ketoconazole shampoo lotion/shampoo
Eubizrival LLC

83462-018

Active Ingredient

Ketoconazole 1% w/w

Purpose

Anti Dandruff Shampoo

Use

controls flaking, scaling and itching associated with dandruff
Warnings
For external use only

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For external use only

Do not use

• on scalp that is damaged or inflamed
• if vou are allergic to ingredients in this product

When Using

• avoid contact with eyes
• if product gets into eyes, rinse thoroughly with water

Stop Use

• rash appears
• condition worsens or does not improve in 2-4 weeks

Ask Doctor

If pregnant or breast-feeding, ask a doctor before use.

Keep Oot Of Reach Of Children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children
12 years and over
• wet hair thoroughly
• apply shampoo, generously lather, rinse thoroughly. Repeat
• use every 3-4 days for up to 8 weeks or as directed by a doctor. Then use only as needed to control dandruff

Children under 12 years old • Ask a doctor

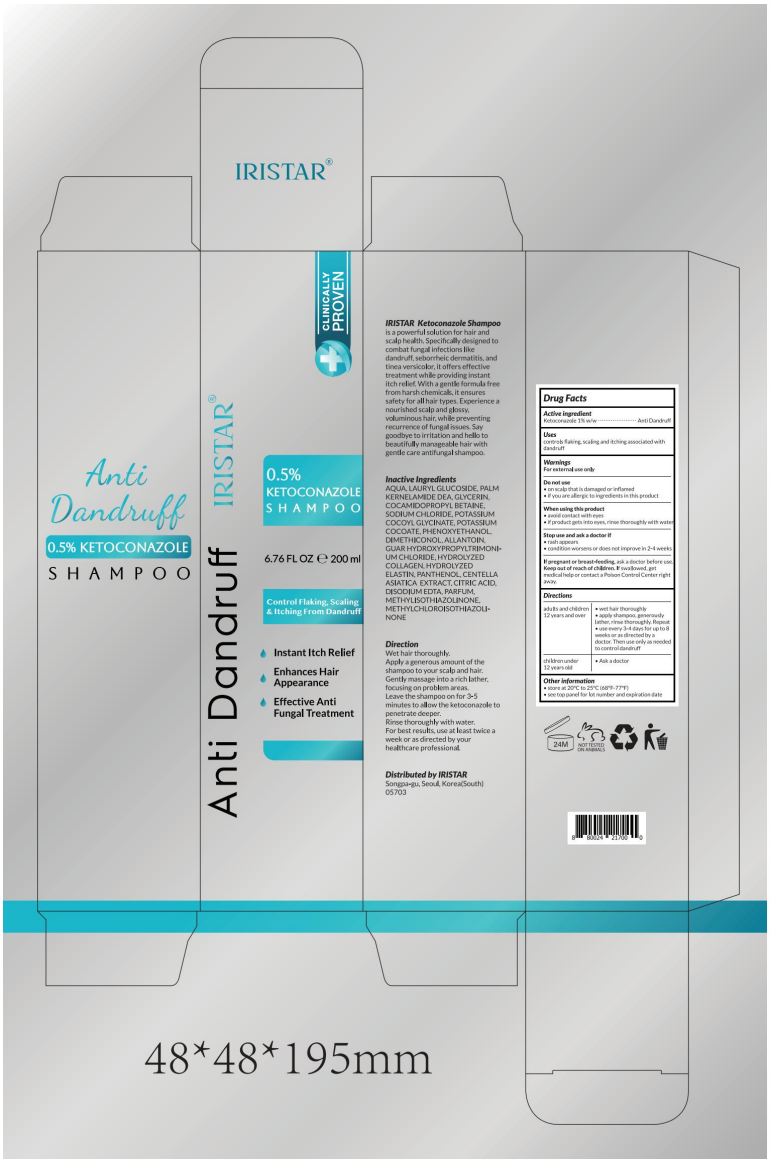
Other information

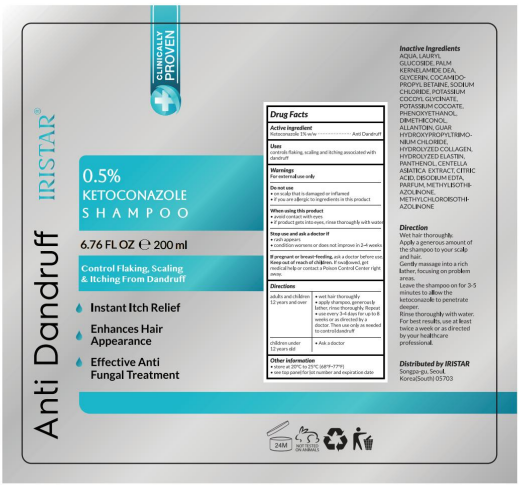
• store at 20°C to 25°C (68°F-77°F)
• see top panel for lot number and expiration date

Inactive ingredients

AQUA, LAURYL GLUCOSIDE, PALM KERNELAMIDE DEA, GLYCERIN, COCAMIDOPROPYL BETAINE, SODIUM CHLORIDE, POTASSIUM COCOYL GLYCINATE, POTASSIUM COCOATE, PHENOXYETHANOL, DIMETHICONOL, ALLANTOIN, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, HYDROLYZED COLLAGEN, HYDROLYZED ELASTIN, PANTHENOL, CENTELLA ASIATICA EXTRACT, CITRIC ACID, DISODIUM EDTA, PARFUM, METHYLISOTHIAZOLINONE, METHYLCHLOROISOTHIAZOLINONE

PRINCIPAL DISPLAY PANEL





130*140mm

IRISTAR ANTI DANDRUFF SHAMPOO.

ketoconazole shampoo lotion/shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83462-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

ALLANTOIN (UNII: 344S277G0Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM COCOATE (UNII: F8U72V8ZXP)	
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
POTASSIUM COCOYL GLYCINATE (UNII: WZ70FUF22U)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
PANTHENOL (UNII: WV9CM0O67Z)	
PALM KERNEL OIL (UNII: B0S90M0233)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
DIMETHICONOL (14000 CST) (UNII: M2HW98ZA4V)	
HYDROLYSED BOVINE COLLAGEN (ENZYMATIC; 2000-5000 MW) (UNII: 5WE8P977RQ)	
HYDROLYZED BOVINE ELASTIN (BASE; 1000 MW) (UNII: ZR28QKN0WT)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83462-018-01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	03/29/2024	

Labeler - Eubizrival LLC (036572203)

Establishment

Name	Address	ID/FEI	Business Operations
Eubizrival LLC		036572203	label(83462-018) , manufacture(83462-018)

Revised: 3/2024 Eubizrival LLC