

NIZORAL A-D- ketoconazole shampoo
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

Nizoral®
A-D KETOCONAZOLE SHAMPOO 1%

Drug Facts

Active ingredient

Ketoconazole 1%

Purpose

Anti-dandruff shampoo

Uses

controls flaking, scaling and itching associated with dandruff

Warnings

For external use only

Do not use

- on scalp that is broken or inflamed
- if you are allergic to ingredients in this product

When using this product

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

Stop use and ask a doctor if

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

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

Keep out 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	<ul style="list-style-type: none">▪ 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.
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children under 12 years

■ ask a doctor

Other information

- store between 35° and 86°F (2° and 30°C)
- protect from light
- protect from freezing
- see top panel for lot number and expiration date

Inactive ingredients

acrylic acid polymer (carbomer 1342), butylated hydroxytoluene, cocamide MEA, FD&C Blue #1, fragrance, glycol distearate, polyquaternium-7, quaternium-15, sodium chloride, sodium cocoyl sarcosinate, sodium hydroxide and/or hydrochloric acid, sodium laureth sulfate, tetrasodium EDTA, water-

Questions or comments?

call 1-800-962-5357

PRINCIPAL DISPLAY PANEL

NON-PRESCRIPTION STRENGTH

NDC 50580-895-04

Nizoral®

A-D KETOCONAZOLE SHAMPOO 1%

***Anti-Dandruff
Shampoo***

CONTROLS FLAKING,
SCALING AND ITCHING

The Freedom Will Go To Your Head

4 FL OZ (125 mL)



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NDC 50580-895-04

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Anti-Dandruff Shampoo

CONTROLS FLAKING, SCALING AND ITCHING

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4 FL OZ (125 mL)



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Distributed by:



McNeil Consumer Healthcare
DIVISION OF
MCNEIL - PPC, INC.
FORT WASHINGTON,
PA 19034 USA

Made in Belgium
US Patent No. 5,456,851.

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Nizoral[®]
A-D KETOCONAZOLE SHAMPOO 1%



NIZORAL A-D
ketoconazole shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-895
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ketoconazole (UNII: R9400W927I) (Ketoconazole - UNII:R9400W927I)	Ketoconazole	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Carbomer copolymer type b (allyl pentaerythritol crosslinked) (UNII: 809Y72KV36)	
Butylated hydroxytoluene (UNII: 1P9D0Z171K)	
Coco Monoethanolamide (UNII: C80684146D)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
Glycol Distearate (UNII: 13W7MDN21W)	
hydrochloric acid (UNII: QTT17582CB)	
Quaternium-15 (UNII: E40U03LEM0)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sodium laureth-3 sulfate (UNII: BPV390UAP0)	
Edetate Sodium (UNII: MP1J8420LU)	
Water (UNII: 059QF0K00R)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
SODIUM COCOYL SARCOSINATE (UNII: 1R9DUY89CZ)	

Product Characteristics

Color	BLUE (opaque, pearlescent blue to blue green)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-895-04	1 in 1 CARTON	04/01/1999	
1		125 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-895-07	1 in 1 CARTON	04/01/1999	
2		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50580-895-14	1 in 1 CARTON	04/01/1999	
3		125 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:50580-895-15	10 in 1 CARTON	04/01/1999	
4		6 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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NDA	NDA020310	04/01/1999	
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Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 12/2019

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division