

NIZORAL- ketoconazole shampoo
Kramer Laboratories

Drug Facts

Active ingredient	Purpose
Ketoconazole 1% w/w	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 the 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
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	doctor. Then use only as needed to control dandruff
children under 12 years	<ul style="list-style-type: none"> 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

benzyl alcohol, BHT, blue 1, citric acid, cocamide MEA, fragrance, glycol distearate, hydrochloric acid, hydroxypropyl methylcellulose, polyquaternium-7, sodium benzoate, sodium chloride, sodium cocoyl sarcosinate, sodium hydroxide, sodium laureth sulfate, tetrasodium EDTA, water

Questions or comments?

call **1-800-824-4894**

PRINCIPAL DISPLAY PANEL

Nizoral®

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN
to control flaking, scaling and
itching from dandruff

CONTROLS
fungus that can cause dandruff

CLEAN
fresh scent

7 fl oz (200mL)

What Causes Dandruff?

Dandruff can have many causes. A fungus found on every human head is often associated with dandruff.

How Does Nizoral® Anti-Dandruff Work?

NIZORAL®

Anti-Dandruff is the only over-the-counter anti-dandruff shampoo that has Ketoconazole, an effective antifungal. Ketoconazole works by controlling fungus often associated with dandruff, and once the fungus is controlled, so are your dandruff symptoms.

Use Nizoral® Anti-Dandruff just twice a week to control your dandruff symptoms.

Before use, read all label information. If you have a drug reaction, contact a doctor and report it by calling:
1.800.824.4894

KRAMER
LABORATORIES

Made in Canada
Distributed by:
Kramer Laboratories, Inc.
Bridgewater, NJ 08807
USA

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LABORATORIES, INC.

Lot:

Exp:

P819B46100

Nizoral®

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

CONTROLS

fungus that can cause dandruff



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Anti-Dandruff Shampoo

CLINICALLY PROVEN

to control flaking, scaling and
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CONTROLS

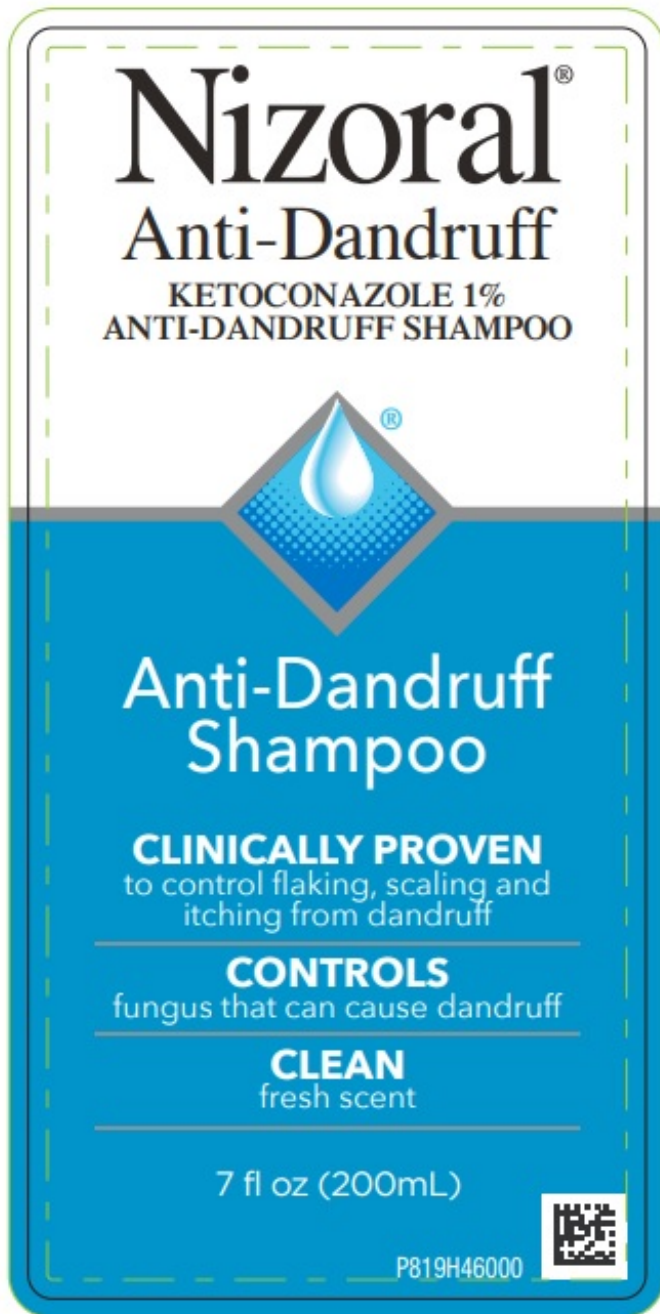
fungus that can cause dandruff

CLEAN

fresh scent

7 fl oz (200mL)

P819H46000



Nizoral®

**Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN
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CONTROLS

fungus that can cause dandruff

CLEAN

fresh scent

4 fl oz (125mL)

P809H45000



Nizoral[®]

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Anti-Dandruff

Shampoo

CLINICALLY PROVEN

to control flaking, scaling and
itching from dandruff

CONTROLS

fungus that can cause dandruff

CLEAN

fresh scent

11 fl oz (325mL)

P829H47000

Nizoral[®]

Anti-Dandruff

KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Anti-Dandruff Shampoo

CLINICALLY PROVEN

to control flaking, scaling
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CONTROLS

fungus that can
cause dandruff

CLEAN

fresh scent

11 fl oz (325mL)

P829H47000



Nizoral[®]

Anti-Dandruff

KETOCONAZOLE 1%

ANTI-DANDRUFF SHAMPOO

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN

to control flaking, scaling and
itching from dandruff

CONTROLS

fungus that can cause dandruff

CLEAN

fresh scent

14 fl oz (400 mL)

P839H48000

Nizoral[®]

Anti-Dandruff

KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Anti-Dandruff Shampoo

CLINICALLY PROVEN

to control flaking, scaling
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fungus that can
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fresh scent

14 fl oz (400mL)

P839H48000



SAMPLE

Nizoral[®]

Anti-Dandruff

KETOCONAZOLE 1%

ANTI-DANDRUFF SHAMPOO

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN

to control flaking, scaling and
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fresh scent

0.4 fl oz (12 mL)

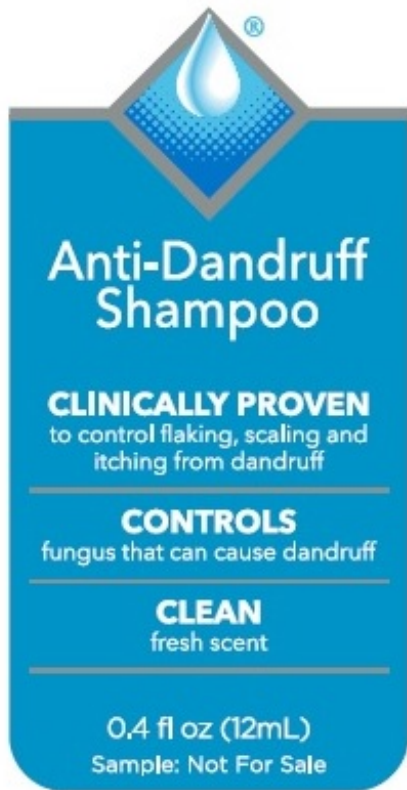
Sample Not For Sale

SAMPLE

Nizoral[®]

Anti-Dandruff

KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Nizoral[®]

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

VALUE SIZE - TWO 11 OZ BOTTLES

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN
to control flaking, scaling and
itching from dandruff

CONTROLS

fungus that can cause dandruff

CLEAN

fresh scent

2 Bottles: 11 fl oz (325 mL) each

Total 22 fl oz (650 mL)

**Use Nizoral® Anti-Dandruff
just twice a week to control
your dandruff symptoms.**

What Causes Dandruff?

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How Does Nizoral® Anti-Dandruff Work?

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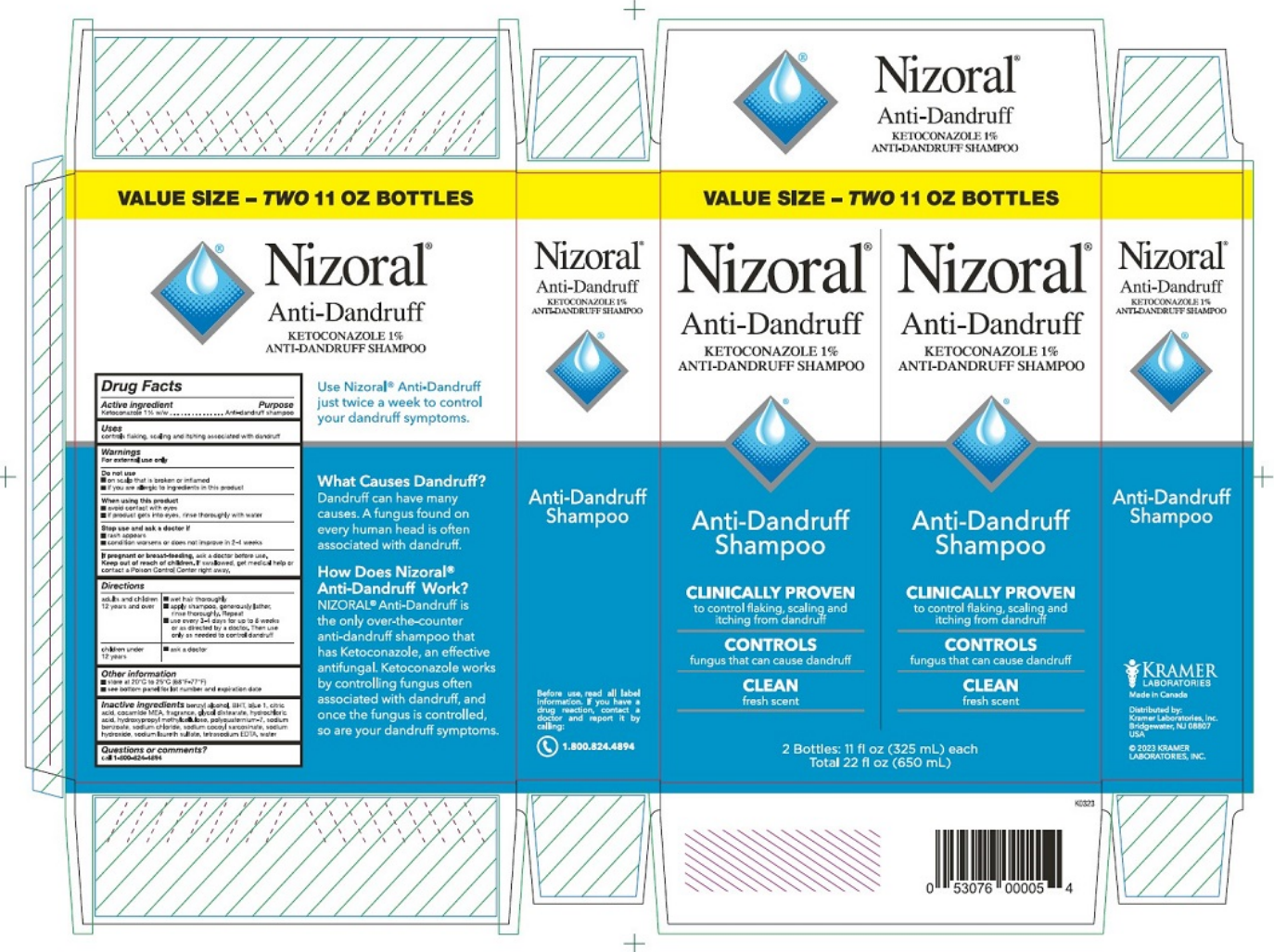
Anti-Dandruff Shampoo

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Bridgewater, NJ 08807
USA



NIZORAL
ketoconazole shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-196
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
Benzyl Alcohol (UNII: LKG8494WBH)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Fd&C Blue No. 1 (UNII: H3R47K3TBD)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Coco Monoethanolamide (UNII: C80684146D)	
Glycol Distearate (UNII: 13W7MDN21W)	
Hydrochloric Acid (UNII: QTT17582CB)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Polyquaternium-7 (70/30 Acrylamide/Dadmac; 1600000 Mw) (UNII: 0L414VCS5Y)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Cocoyl Sarcosinate (UNII: 1R9DUY89CZ)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sodium Laureth-3 Sulfate (UNII: BPV390UAP0)	
Edetate Sodium (UNII: MP1J8420LU)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-196-33	1 in 1 CARTON	06/16/2022	
1		125 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55505-196-40	1 in 1 CARTON	06/16/2022	
2		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55505-196-64	1 in 1 CARTON	06/16/2022	
3		325 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55505-196-65	1 in 1 CARTON	06/16/2022	
4		400 mL in 1 CARTON; Type 0: Not a Combination Product		
5	NDC:55505-196-47	4 mL in 1 PACKET; Type 0: Not a Combination Product	03/01/2024	
6	NDC:55505-196-72	2 in 1 CARTON	12/01/2023	
6		325 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020310	06/16/2022	

Labeler - Kramer Laboratories (122720675)

