

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
--	---

	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

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

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

Shampoo + conditioner

Nizoral®

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

**2-IN-1
Anti Dandruff
Shampoo +
Conditioner**

CLINICALLY PROVEN
to control flaking, scaling and
itching from dandruff

CONTROLS
fungus that can cause dandruff

CONDITIONS

leaves hair soft, smooth & manageable

14 fl oz (400mL)

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.

Nizoral®

Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO

Nizoral® 2-IN-1 Anti-Dandruff Shampoo + Conditioner

is formulated with more conditioning properties to help leave hair soft, smooth, and manageable.

KRAMER
LABORATORIES

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

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LABORATORIES, INC.

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

P238B15000

Lot:

Exp: YYYY-MM

K0524

Exp: YYYY-MM
Lot:

P238B1500



Nizoral
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO

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

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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 ■ 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

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K0324

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Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Shampoo + Conditioner

Nizoral
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Nizoral
Anti-Dandruff
KETOCONAZOLE 1%
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NIZORAL
ketoconazole shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-233
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)	
Sodium Benzoate (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-233-65	400 mL in 1 CARTON; Type 0: Not a Combination Product	11/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020310	11/01/2024	

Labeler - Kramer Laboratories (122720675)