

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

benzyl alcohol, BHT, citric acid, cocamide MEA, FD&C Blue 1, FD&C Yellow 5, 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**

Dist. by:

Kramer Laboratories, Inc., Bridgewater, NJ 08807 USA

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Made in Canada

PRINCIPAL DISPLAY PANEL

Center panel

NEW SCENT!

Nizoral®

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

**PEPPERMINT
COMPLEX +
TEA TREE ESSENCE**

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN

to control flaking, scaling and itching from dandruff

CONTROLS

fungus that can cause dandruff

REFRESHING

peppermint complex
+ tea tree essence

14 fl oz (400 mL)

right panel

**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.

left panel

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.

P221B16000

Lot:

Exp: YYYY-MM



Nizoral®

Anti-Dandruff

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P221H14000

LOT

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LOT

EXP YYYY-MM

P221H1 4000

NIZORAL

ketoconazole shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-232
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
Benzyl Alcohol (UNII: LKG8494WBH)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Coco Monoethanolamide (UNII: C80684146D)	
Fd&C Blue No. 1 (UNII: H3R47K3TBD)	
Fd&C Yellow No. 5 (UNII: I753WB2F1M)	
Glycol Distearate (UNII: 13W7MDN21W)	
Hydrochloric Acid (UNII: QTT17582CB)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Polyquaternium-7 (70/30 Acrylamide/Dadmac; 1600000 Mw) (UNII: 0L414VCS5Y)	
Sodium Benzoate (UNII: OJ245FE5EU)	
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:55505-232-65	400 mL in 1 CARTON; Type 0: Not a Combination Product	10/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020310	10/01/2025	

