

NIZORAL- ketoconazole shampoo
Kramer Laboratories

Drug Facts

Active ingredient	Purpose
Ketoconazole 1%	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, blue 1, citric acid, cocamide MEA, fragrance, glycol distearate, hydrochloric acid, hydroxypropyl methylcellulose, polyquaternium-7, 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® 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.

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

1.800.824.4894

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LABORATORIES

Made in Belgium

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Bridgewater, NJ 08807
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USA
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875



Nizoral®

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN

to control flaking, scaling and itching from dandruff

CONTROLS

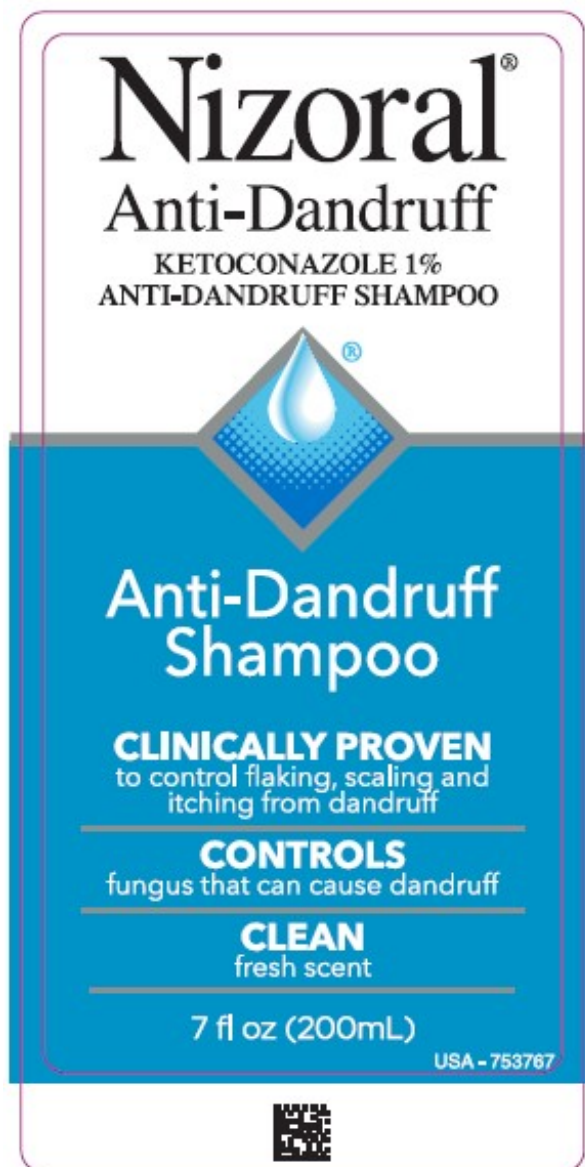
fungus that can cause dandruff

CLEAN

fresh scent

7 fl oz (200mL)

USA -753767



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Made in Belgium

USA - 753768

LOT


EXP

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: 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)	
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 lauryl sulfate, tetrasodium EDTA, water.	
Questions or comments? 1-800-824-4894	

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Made in Belgium USA - 753768

LOT

EXP



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

4 fl oz (125mL)

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® 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.

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Nizoral[®]

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

**Anti-Dandruff
Shampoo**

CLINICALLY PROVEN

to control flaking, scaling and itching from dandruff

CONTROLS

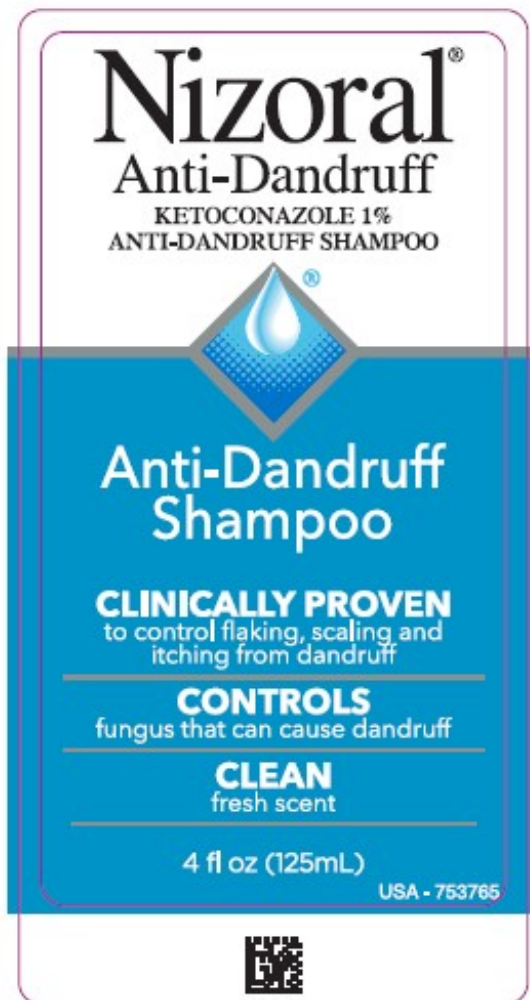
fungus that can cause dandruff

CLEAN

fresh scent

4 fl oz (125mL)

USA -753765



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Made in Belgium

USA - 753766

LOT

EXP

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:	
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)	
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 lauryl sulfate, tetrasodium EDTA, water.	
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LOT

EXP



BUY 2 AND SAVE!

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

2 Bottles: 7 fl oz (200 mL) each
Total 14 fl oz (400 mL)

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

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.

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1.800.824.4894

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Nizoral
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO

BUY 2 AND SAVE!



Nizoral
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO

Drug Facts	
Active ingredient	Purpose
Ketoconazole 1%	Anti-dandruff shampoo
Uses Controls itching, 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	• wet hair thoroughly • apply shampoo, generously lather, rinse thoroughly. Repeat. • use every 2-3 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 bottom panel for lot number and expiration date	
Inactive ingredients benzyl alcohol, BHT, blue 1, citric acid, cocamide MEA, fragrance, glycol distearate, hydroxyacetic acid, hydroxypropyl methylcellulose, polyquaternium-7, sodium chloride, sodium cocoyl sarcosinate, sodium hydroxide, sodium lauryl sulfate, tetrasodium EDTA, water	
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Nizoral
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Anti-Dandruff Shampoo

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

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

Nizoral
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Anti-Dandruff Shampoo

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2 Bottles: 7 fl oz (200 mL) each
Total 14 fl oz (400 mL)

1.800.824.4894

83721



value packs xxx


Nizoral
 Anti-Dandruff
 KETOCONAZOLE 1%
 ANTI-DANDRUFF SHAMPOO

VALUE SIZE
 2 BOTTLES (7 OZ + 4 OZ)



Nizoral
 Anti-Dandruff
 KETOCONAZOLE 1%
 ANTI-DANDRUFF SHAMPOO

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

Drug Facts

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Ketoconazole 1%	Anti-dandruff shampoo

Uses
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 • if you are allergic to ingredients in this product

When using this product
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 • 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

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 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
 • wet hair thoroughly
 • apply shampoo, generously lather, rinse thoroughly. Repeat.
 • use every 3-4 days for up to 6 weeks or as directed by a doctor. Then use only as needed to control dandruff

showe under 12 years
 • ask a doctor

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

Inactive ingredients benzyl alcohol, DHT, blue 1, citric acid, cocamide MEA, fragrance, glycol distearate, hydrochloric acid, hydroxypropyl methylcellulose, polyquaternium-7, sodium chloride, sodium cocoyl sarcosinate, sodium hydroxide, sodium lauryl sulfate, tetrasodium EDTA, water

Questions or comments?
 call 1-800-824-4894

K0721

VALUE SIZE
 2 BOTTLES (7 OZ + 4 OZ)

Nizoral
 Anti-Dandruff
 KETOCONAZOLE 1%
 ANTI-DANDRUFF SHAMPOO



Nizoral
 Anti-Dandruff
 KETOCONAZOLE 1%
 ANTI-DANDRUFF SHAMPOO



Nizoral
 Anti-Dandruff
 KETOCONAZOLE 1%
 ANTI-DANDRUFF SHAMPOO



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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

2 Bottles
 7 fl oz (200 mL) + 4 fl oz (125 mL)
 Total 11 fl oz (325 mL)

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.



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NIZORAL

ketoconazole shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55505-192
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)	
Hypromelloses (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:55505-192-40	1 in 1 CARTON	01/07/2019	
1		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55505-192-33	1 in 1 CARTON	11/01/2019	
2		125 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55505-192-57	2 in 1 CARTON	11/01/2019	
3		1 in 1 CARTON		
3		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		

4	NDC:55505-194-59	2 in 1 CARTON	11/01/2019	
4		325 mL in 1 CARTON; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	NDA020310		01/07/2019	

Labeler - Kramer Laboratories (122720675)

Revised: 12/2024

Kramer Laboratories