

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, 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

© 2022 KRAMER
LABORATORIES, INC.

Lot:

Exp:

P819B46100

Nizoral®

Anti-Dandruff

**KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO**

CONTROLS

fungus that can cause dandruff

Lot: _____
Exp: _____

0019816100



Nizoral[®]
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO

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

Drug Facts

Active ingredient Ketoconazole 1% w/w **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
■ 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

Inactive ingredients benzyl alcohol, BHT, blue 1, citric acid, cocamide MEA, fragrances, 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

Nizoral[®]
Anti-Dandruff
KETOCONAZOLE 1%
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

7 fl oz (200mL)

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

1.800.824.4894



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

© 2022 KRAMER LABORATORIES, INC.

Nizoral[®]
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO

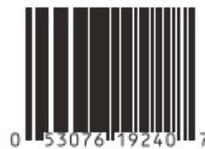


What Causes Dandruff?

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**

**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)

P819H46000

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)



P819H46000

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)

P809H45000



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

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

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
and itching from dandruff

CONTROLS
fungus that can
cause dandruff

CLEAN
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
itching from dandruff

CONTROLS

fungus that can cause dandruff

CLEAN

fresh scent

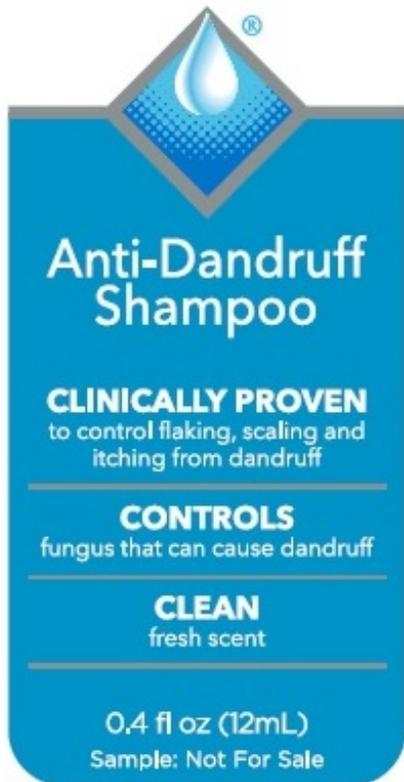
0.4 fl oz (12 mL)

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?

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.

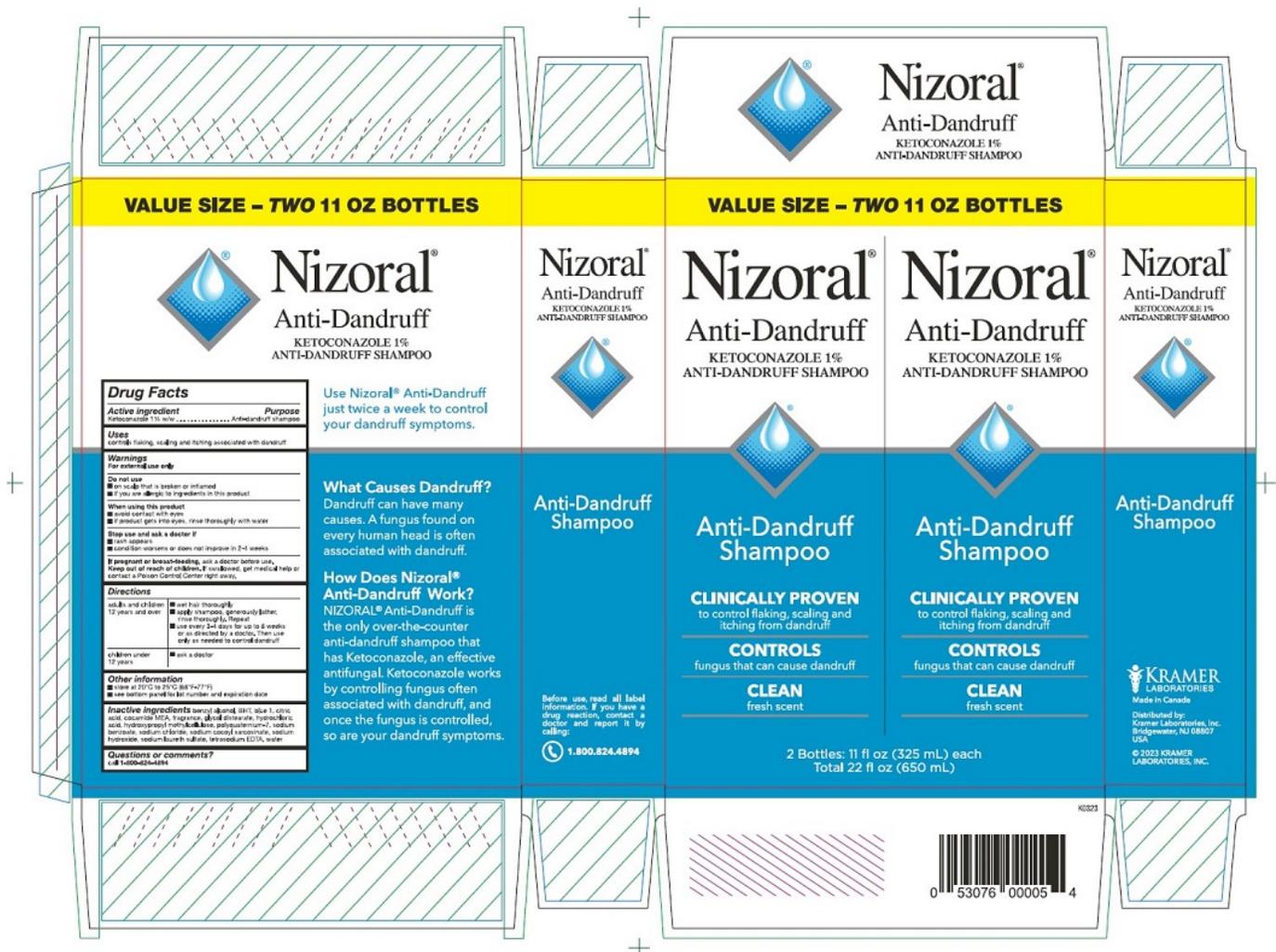
Anti-Dandruff Shampoo

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



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

19 fl oz (562mL)

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

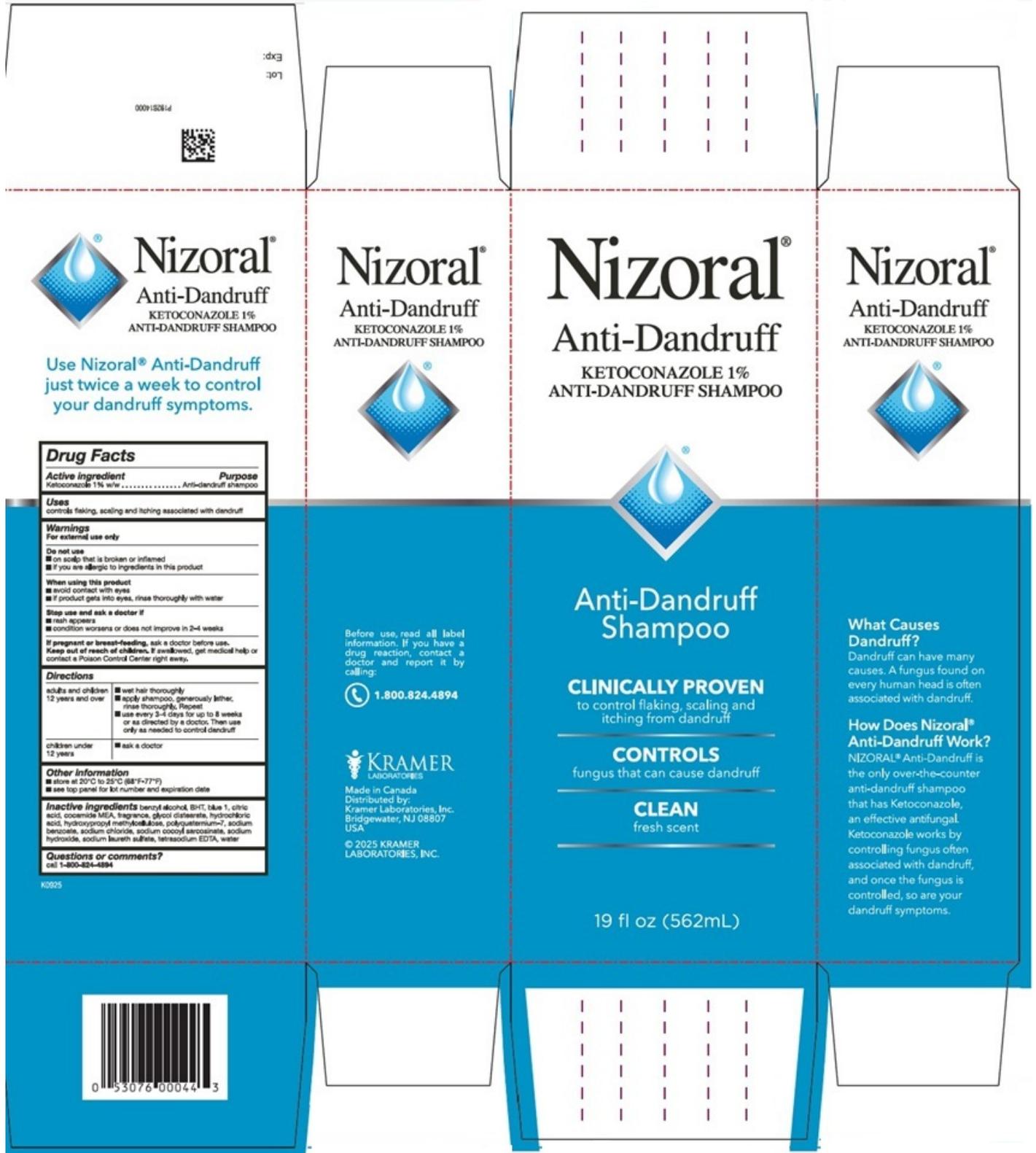
Made in Canada
Distributed by:
Kramer Laboratories, Inc.
Bridgewater, NJ 08807
USA

© 2025 KRAMER
LABORATORIES, INC.

P192B14000

Lot:

Exp:



Exp:
Lot:

P192B14000



Nizoral®
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO

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

Nizoral®
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Nizoral®
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Nizoral®
Anti-Dandruff
KETOCONAZOLE 1%
ANTI-DANDRUFF SHAMPOO



Drug Facts

Active ingredient Ketoconazole 1% w/w
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
■ 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 directed 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

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?
call 1-800-824-4894

K0925

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

📞 1.800.824.4894



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

© 2025 KRAMER LABORATORIES, INC.

Anti-Dandruff Shampoo

CLINICALLY PROVEN
to control flaking, scaling and itching from dandruff

CONTROLS
fungus that can cause dandruff

CLEAN
fresh scent

19 fl oz (562mL)

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.



0 53076 00044 3

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	10/31/2025
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		
7	NDC:55505-196-85	1 in 1 CARTON	01/12/2026	
7		562 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:55505-196-68	3 in 1 CARTON	10/15/2022	
8		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:55505-196-57	2 in 1 CARTON	04/29/2023	
9		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:55505-196-84	2 in 1 CARTON	06/01/2025	
10		400 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)

Revised: 12/2025

Kramer Laboratories