

**NIZORAL- ketoconazole shampoo**  
**Kramer Laboratories**

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**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
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"><li>▪ wet hair thoroughly</li><li>▪ apply shampoo, generously lather, rinse thoroughly. Repeat</li><li>▪ use every 3-4 days for up to 8 weeks or as directed by a</li></ul>
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	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, 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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USA

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USA  
753769  
875



**Nizoral®**

**Anti-Dandruff**

**KETOCONAZOLE 1%  
ANTI-DANDRUFF SHAMPOO**

**Anti-Dandruff  
Shampoo**

**CLINICALLY PROVEN**

to control flaking, scaling and itching from dandruff

**CONTROLS**

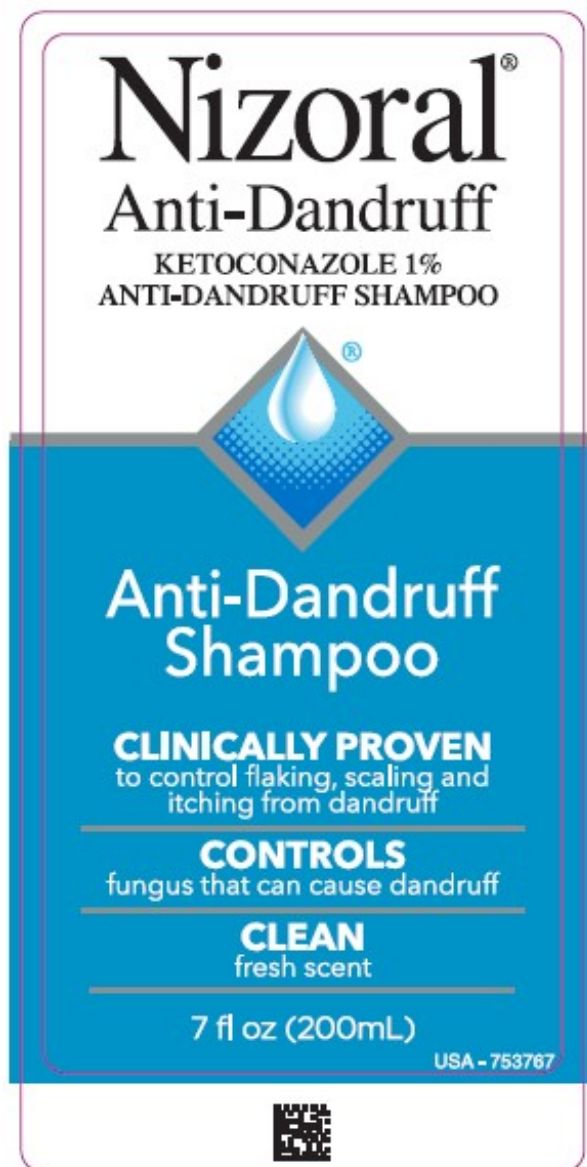
fungus that can cause dandruff

**CLEAN**

fresh scent

7 fl oz (200mL)

USA -753767



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USA - 753768

LOT


EXP

<b>Active ingredient</b>	<b>Purpose</b>
Ketoconazole 1% w/w	Anti-dandruff shampoo
<b>Uses</b> controls flaking, scaling and itching associated with dandruff	
<b>Warnings</b> 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.	
<b>Directions</b>	
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	
<b>Other information</b>	
store at 20°C to 25°C (68°F-77°F)	
<b>Inactive ingredients</b> 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.	
<b>Questions or comments?</b> 1-800-824-4894	

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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<sup>®</sup>**

**Anti-Dandruff**

**KETOCONAZOLE 1%  
ANTI-DANDRUFF SHAMPOO**

**Anti-Dandruff  
Shampoo**

**CLINICALLY PROVEN**

to control flaking, scaling and itching from dandruff

**CONTROLS**

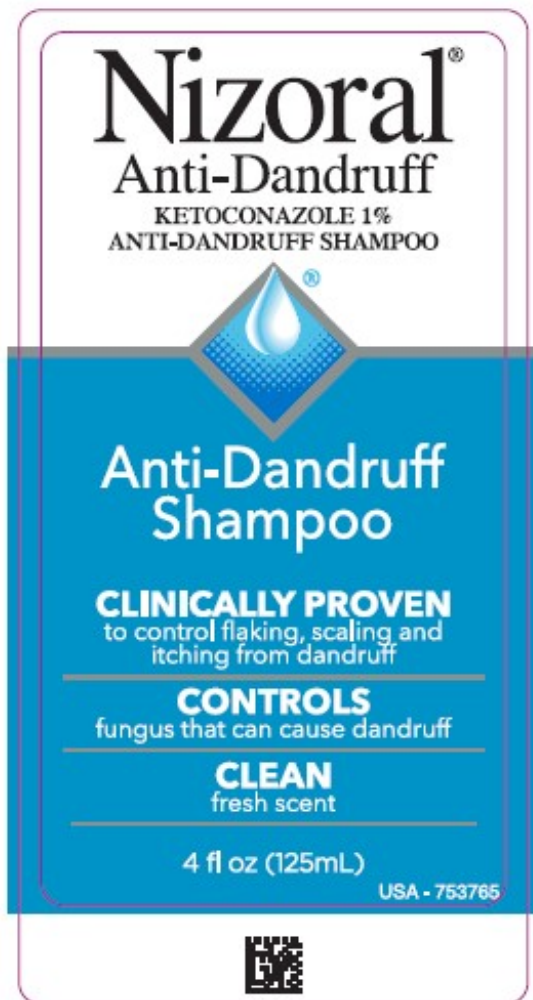
fungus that can cause dandruff

**CLEAN**

fresh scent

4 fl oz (125mL)

USA -753765



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USA - 753766

LOT

EXP

Active ingredient	Purpose
Ketoconazole 1% w/w	Anti-dandruff shampoo
<b>Uses</b> controls flaking, scaling and itching associated with dandruff	
<b>Warnings</b> 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.	
<b>Directions</b>	
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	
<b>Other information</b>	
store at 20°C to 25°C (68°F-77°F)	
<b>Inactive ingredients</b> 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.	
<b>Questions or comments?</b> 1-800-824-4894	
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Made in Belgium	

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<sup>®</sup> 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<sup>®</sup> Anti-Dandruff Work?**

NIZORAL<sup>®</sup> 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**<sup>®</sup>  
Anti-Dandruff  
KETOCONAZOLE 1%  
ANTI-DANDRUFF SHAMPOO

**BUY 2 AND SAVE!**



**Nizoral**<sup>®</sup>  
Anti-Dandruff  
KETOCONAZOLE 1%  
ANTI-DANDRUFF SHAMPOO

Drug Facts	
Active ingredient	Purpose
Ketoconazole 1%	Antifungal
<b>Uses</b> Controls itching, scaling and itching associated with dandruff	
<b>Warnings</b> For external use only	
<b>Do not use</b> • on scalp that is broken or inflamed • if you are allergic to ingredients in this product	
<b>When using this product</b> • avoid contact with eyes • if product gets into eyes, rinse thoroughly with water	
<b>Stop use and ask a doctor if</b> • rash appears • condition worsens or does not improve in 2-4 weeks	
<b>If pregnant or breast-feeding, ask a doctor before use.</b> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
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
<b>Other information</b> • store at 20°C to 25°C (68°F-77°F) • see bottom panel for lot number and expiration date	
<b>Inactive ingredients</b> 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	
<b>Questions or comments?</b> call 1-800-824-4894	

Use Nizoral<sup>®</sup> 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<sup>®</sup> Anti-Dandruff Work?**  
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**Nizoral**<sup>®</sup>  
Anti-Dandruff  
KETOCONAZOLE 1%  
ANTI-DANDRUFF SHAMPOO



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

**BUY 2 AND SAVE!**

**Nizoral**<sup>®</sup>  
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**<sup>®</sup>  
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)

**Nizoral**<sup>®</sup>  
Anti-Dandruff  
KETOCONAZOLE 1%  
ANTI-DANDRUFF SHAMPOO



Anti-Dandruff Shampoo

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0 53076 19237 5

value packs xxx

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

**VALUE SIZE**  
 2 BOTTLES (7 OZ + 4 OZ)

**VALUE SIZE**  
 2 BOTTLES (7 OZ + 4 OZ)

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

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

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 ANTI-DANDRUFF SHAMPOO

**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	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  
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**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 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

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

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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.



# NIZORAL

ketoconazole shampoo

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55505-192
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Ketoconazole</b> (UNII: R9400W927I) (Ketoconazole - UNII:R9400W927I)	Ketoconazole	10 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>Butylated Hydroxytoluene</b> (UNII: 1P9D0Z171K)	
<b>Fd&amp;C Blue No. 1</b> (UNII: H3R47K3TBD)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>Coco Monoethanolamide</b> (UNII: C80684146D)	
<b>Glycol Distearate</b> (UNII: 13W7MDN21W)	
<b>Hydrochloric Acid</b> (UNII: QTT17582CB)	
<b>Hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>Polyquaternium-7 (70/30 Acrylamide/Dadmac; 1600000 Mw)</b> (UNII: 0L414VCS5Y)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Sodium Cocoyl Sarcosinate</b> (UNII: 1R9DUY89CZ)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Sodium Laureth-3 Sulfate</b> (UNII: BPV390UAP0)	
<b>Edetate Sodium</b> (UNII: MP1J8420LU)	
<b>Water</b> (UNII: 059QF0KO0R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA020310		01/07/2019	

**Labeler - Kramer Laboratories (122720675)**

Revised: 12/2023

Kramer Laboratories