QUALITY CHOICE VAGINAL ANTI-ITCH MAXIMUM STRENGTH - benzocaine and resorcinol cream

Chain Drug Marketing Association (CDMA)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients:

Benzocaine 20%

Resorcinol 3%

Purpose

External analgesic

External analgesic

Use:

temporarily relieves itching.

Warnings

For external use only

When using this product avoid contact with the eyes

Stop use and ask a doctor if condition worsens or if symptoms persist for more than 7 days, or clear up and occur again within a few days, discontinue use of this product and consult a physician.

Do not apply over large areas of the body

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 of age and older

apply a fingertip amount (approximately 1 inch strip) to the affected area not more than 3 to 4 times daily

Children under 12 years

ask a doctor

Other information

store at 20°- 25°C (68°- 77°F)

Inactive ingredients

purified water, mineral oil, isopropyl palmitate, cetyl alcohol, PEG-100 stearate, glyceryl stearate, isopropyl myristate, lanolin, methyl-4 hydroxybenzoate, carbomer, fragrance, disodium EDTA, triethanolamine, propylene glycol, stearic acid corn oil, stearyl alcohol, vitamin A, E & D, aloe vera gel.

Principal Display Panel - 1 oz. Carton Label

 $\mathbf{QC}_{\mathbb{R}}$

QUALITY

CHOICE

*Compare to active ingredients in VAGISIL® Maximum Strength

Maximum Strength

Vaginal Anti-Itch Cream

Medicated

20% Benzocaine | Resorcinol 3%

Long-Lasting Relief from:

Every Day Itching and Irritating Vaginal Conditions

Relieves Every Day Itch

 $\mathbf{QC}_{\mathbb{R}}$

QUALITY

CHOICE

Vaginal Anti-Itch Cream

Maximum Strength

1 OZ NET WT (28.4g)





*Compare to active ingredients in VAGISIL® **Maximum Strength**

Maximum Strength

Vaginal Anti-Itch Cream

Medicated

20% Benzocaine | Resorcinol 3%

Long-Lasting Relief from:

Every Day Itching and Irritating Vaginal Conditions

Relieves Every Day Itch



Vaginal Anti-Itch Cream

Maximum Strength

OZ NET WT (28.4g)



Purpose

Distributed by C.D.M.A., Inc. 43157 W. Nine Mile Novi, MI 48376-0995 Questions: 248-449-9300

*This product is not manufactured or distributed by Combe, Inc., owner of the registered trademark Vagisil®.



alcohol, vitamin A, E & D, aloe vera gel.

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SenimeW

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External analgesic External analgesic

Active ingredients
Benzocaine 20%

Drug Facts







Principal Display Panel - 1 oz. Tube Label

 $\mathbf{QC}_{\mathbb{R}}$

QUALITY

CHOICE

*Compare to active ingredients in VAGISIL® Maximum Strength

Vaginal Anti-Itch Cream

Maximum Strength

20% Benzocaine | Resorcinol 3%

Long-Lasting Relief from:

Every Day Itching and Irritating Vaginal Conditions

1 OZ NET WT (28.4g)



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Vaginal Anti-Itch Cream

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OZ NET WT (28.4g)

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Use: temporarily relieves itching.

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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 of age and older: apply a fingertip amount (approximately 1 inch strip) to the affected area not more than 3 to 4 times daily. **Children under 12 years of age:** Ask a doctor.

Other information: store at 20°- 25°C (68°- 77°F). Inactive ingredients: purified water, mineral oil, isopropyl palmitate, cetyl alcohol, PEG-100 stearate, glyceryl stearate, isopropyl myristate, lanolin, methyl-4 hydroxybenzoate, carbomer, fragrance, disodium EDTA, triethanolamine, propylene glycol, stearic acid corn oil, stearyl alcohol, vitamin A, E & D, aloe vera gel.

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QUALITY CHOICE VAGINAL ANTI-ITCH MAXIMUM STRENGTH

benzocaine and resorcinol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-965
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	200 mg in 1 g	
RESORCINOL (UNII: YUL4L094HK) (RESORCINOL - UNII:YUL4L094HK)	RESORCINOL	30 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
Aloe Vera Leaf (UNII: ZY81Z83H0X)		
Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: 809 Y72KV36)		
Cetyl Alcohol (UNII: 936JST6JCN)		
Edetate Disodium (UNII: 7FLD91C86K)		
Glyceryl Monostearate (UNII: 230 O U9 XXE4)		
Isopropyl Myristate (UNII: 0 RE8 K4LNJS)		
Isopropyl Palmitate (UNII: 8CRQ2TH63M)		
Lanolin (UNII: 7EV65EAW6H)		
Potassium Methylparaben (UNII: M64U971IB0)		
Mineral Oil (UNII: T5L8T28FGP)		
PEG-100 Stearate (UNII: YD01N1999R)		
Propylene Glycol (UNII: 6DC9Q167V3)		
Water (UNII: 059QF0KO0R)		
Stearic Acid (UNII: 4ELV7Z65AP)		
Stearyl Alcohol (UNII: 2KR89I4H1Y)		
Trolamine (UNII: 9O3K93S3TK)		
Vitamin A (UNII: 81G40H8B0T)		
Vitamin D (UNII: 9 VU1KI44GP)		
.AlphaTocopherol (UNII: H4N855PNZ1)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63868-965-01	1 in 1 CARTON	04/28/2014	
1	28 g in 1 TUBE; Type 0: Not a Combination Product		

	Marketing Inform	nation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part348	04/28/2014	

Labeler - Chain Drug Marketing Association (CDMA) (011920774)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natural Essentials		947484713	MANUFACTURE(63868-965)	

Revised: 1/2018 Chain Drug Marketing Association (CDMA)