

LEADER ANTI-ITCH MAXIMUM STRENGTH - benzocaine and resorcinol cream
Cardinal Health

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 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. Also, do not use if you have an unusual or abnormal vaginal discharge except under the supervision of 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 and older

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

Children under 12 years

consult a doctor

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe vera gel, carbomer, cetyl alcohol, disodium EDTA, fragrance, glyceryl stearate, isopropyl

myristate, isopropyl palmitate, lanolin, methyl-4 hydroxybenzoate, mineral oil, PEG-100 stearate, propylene glycol, purified water, stearic acid com oil, stearyl alcohol, triethanolamine, vitamin A, E & D.

Principal Display Panel - 28 g Carton Label

NDC 49781-092-01

Compare to Vagisil®

Maximum Strength Cream

active ingredients*

LEADER®

MAXIMUM STRENGTH

Anti-Itch Vaginal Cream

Fast, Long-Lasting Relief from Intense Itch

Associated with irritating Vaginal Conditions

For Feminine Itching & Irritation

Fast, Long-Lasting Relief from Intense Itch associated with:

Discharge and Irritating Vaginal Conditions

Satisfaction Guaranteed

NET WT 1 OZ (28g)

NDC 49781-092-01



Compare to Vagisil® Maximum Strength Cream active ingredients*

MAXIMUM STRENGTH

Anti-Itch Vaginal Cream

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MAXIMUM STRENGTH
Anti-Itch Vaginal Cream

Fast, Long-Lasting Relief from Intense Itch



MAXIMUM STRENGTH

Anti-Itch Vaginal Cream

Fast, Long-Lasting Relief from Intense Itch

Associated with Irritating Vaginal Conditions



NET WT 1 OZ (28g)

DISTRIBUTED BY
CARDINAL HEALTH, DUBLIN, OHIO 43017
CIN 4952164
www.myleader.com 1-800-200-6313

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

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



NO COAT AREA

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Resorcinol 3%
External Analgesic

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store at 20°-25°C (68°-77°F)

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

Purpose
External Analgesic

Fast, Long-Lasting Relief from Intense Itch Associated with Irritating Vaginal Conditions

Anti-Itch Vaginal Cream

Principal Display Panel - 28 g Tube Label

NDC 49781-092-01

Compare to Vagisil®

Maximum Strength Cream

active ingredients*

LEADER®

MAXIMUM STRENGTH

Anti-Itch Vaginal Cream

Fast, Long-Lasting Relief from Intense Itch

Associated with irritating Vaginal Conditions

Satisfaction Guaranteed

NET WT 1 OZ (28g)

NDC 49781-092-01

LEADER®

MAXIMUM STRENGTH

Anti-Itch Vaginal Cream

Fast, Long-Lasting Relief from Intense Itch
Associated with Irritating Vaginal Conditions

NET WT 1 OZ (28g)

Compare to Vagisil®
Maximum Strength Cream
active ingredients*

SATISFACTION GUARANTEED

Active ingredients: Benzocaine 20%, Resorcinol 3%.
Use: temporarily relieves itching.
Warnings: For external use only. Avoid contact with the eyes. 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 of age: Ask a doctor.
Other information: store at 20°- 25°C (68°- 77°F).

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

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LEADER ANTI-ITCH MAXIMUM STRENGTH

benzocaine and resorcinol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-092
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: 809Y72KV36)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
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: 2KR89I4HIY)	
Trolamine (UNII: 9O3K93S3TK)	
Vitamin A (UNII: 81G40H8B0T)	
Vitamin D (UNII: 9VU1KI44GP)	
.Alpha.-Tocopherol (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-092-01	1 in 1 CARTON	05/19/2013	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	05/19/2013	

Labeler - Cardinal Health (097537435)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Essentials		947484713	MANUFACTURE(4978 1-092)

Revised: 1/2018

Cardinal Health