

LEADER ANTI-ITCH REGULAR 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 5%

Resorcinol 2%

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, mineral oil, methyl-4 hydroxybenzoate, PEG-100 stearate, propyl 4-hydroxybenzoate, propylene glycol, purified water, triethanolamine, vitamin A, E & D.

Principal Display Panel - 28 g Carton Label

NDC 49781-093-01

Compare to Vagisil®

Regular Strength Cream

active ingredients*

LEADER®

REGULAR STRENGTH

Anti-Itch Vaginal Cream

Fast Relief from Everyday Itch

Associated with Periods, Clothing, Perspiration

For Feminine Itching & Irritation

*Fast Relief from Everyday Itch associated with
Periods, Clothing, Perspiration*

Satisfaction Guaranteed

NET WT 1 OZ (28g)

NDC 49781-093-01



LEADER

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REGULAR STRENGTH

Anti-Itch Vaginal Cream

*Fast Relief from Everyday Itch
Associated with Periods, Clothing, Perspiration*

NET WT 1 OZ (28g)

DISTRIBUTED BY
CARDINAL HEALTH, DUBLIN, OHIO 43017
CIN 4952149
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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Drug Facts	Active ingredients Benzocaine 5% Resorcinol 2%External AnalgesicExternal Analgesic
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 2 years and older apply a fingertip amount (approximately 1-inch strip) to affected area not more than 3 to 4 times daily. Children under 2 years consult a doctor
Other information store at 20°-25°C (68°-77°F)	Inactive ingredients triethanolamine, vitamin A, D & E mineral oil, methyl 4-hydroxybenzoate, PEG-100 stearate, propyl 4-hydroxybenzoate, propylene glycol, purified water, aloe vera gel, carbomer, cetyl alcohol, disodium EDTA, fragrance, glyceryl stearate, isopropyl myristate, isopropyl palmitate, lanolin,

*Fast Relief
from Everyday Itch
Associated with Periods, Clothing, Perspiration*

REGULAR STRENGTH
**Anti-Itch
Vaginal Cream**

Principal Display Panel - 28 g Tube Label

NDC 49781-093-01

Compare to Vagisil®

Regular Strength Cream

active ingredients*

LEADER®

REGULAR STRENGTH

Anti-Itch Vaginal Cream

Fast Relief from Everyday Itch

associated with Periods, Clothing, Perspiration

Satisfaction Guaranteed

NET WT 1 OZ (28g)

NDC 49781-093-01

LEADER®

REGULAR STRENGTH

Anti-Itch Vaginal Cream

Fast Relief from Everyday Itch
associated with Periods, Clothing, Perspiration

NET WT 1 OZ (28g)

SATISFACTION GUARANTEED

Compare to Vagisil®
Regular Strength Cream
active ingredients*

Active ingredients: Benzocaine 5%, Resorcinol 2%.
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, mineral oil, methyl 4-hydroxybenzoate, PEG-100 stearate, propyl 4-hydroxybenzoate, propylene glycol, purified water, triethanolamine, vitamin A, D & E.

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LEADER ANTI-ITCH REGULAR STRENGTH

benzocaine and resorcinol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-093
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	50 mg in 1 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	20 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)	
Mineral Oil (UNII: T5L8T28FGP)	
Potassium Methylparaben (UNII: M64U971IB0)	
PEG-100 Stearate (UNII: YD01N1999R)	
Propylparaben Sodium (UNII: 625NNB0G9N)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0K00R)	
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:49781-093-01	1 in 1 CARTON	05/19/2014	
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	05/19/2014	

Labeler - Cardinal Health (097537435)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Essentials		947484713	MANUFACTURE(49781-093)

Revised: 1/2018

Cardinal Health