

LEADER REGULAR STRENGTH ANTI-ITCH- 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

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 (1-800-222-1222) 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, propyl 4-hydroxybenzoate, propylene glycol, purified water, triethanolamine, vitamin A, D & E.

Principal Display Panel - 50 mg Carton Label

LEADER™

NDC 70000-0370-1

Regular Strength

Anti-Itch

Vaginal Cream

Benzocaine, 5% | Resorcinol, 2%

External Analgesic

LEADERTM

NDC 70000-0370-4

Regular Strength

Anti-Itch Vaginal Cream

Benzocaine, 5% | Resorcinol, 2%
External Analgesic

LOT
EXP

For Feminine Itching

Relief from Everyday Itch Associated
with Periods, Clothing, Perspiration

COMPARE TO
VAGISIL[®] REGULAR
STRENGTH CREAM
active ingredients*

100% Money Back Guarantee

NET WT 1 OZ (28g)



CIN 544214 REV. 5/19

Questions and comments?
1-800-351-0177
Weekdays
9:00am - 5:00 pm (EST).



Return to place of purchase.



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

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LEADERTM

Relief from Everyday Itch
Associated with Periods,
Clothing, Perspiration

Principal Display Panel - 50 mg Tube Label

LEADER™

NDC 70000-0370-1

Regular Strength

Anti-Itch Vaginal Cream

Benzocaine, 5% | Resorcinol, 2%

External Analgesic

Relief from Everyday Itch

Associated with Periods, Clothing, Perspiration

NET WT 1 OZ (28 g)

NDC 70000-0370-1

LEADER™

Regular Strength

Anti-Itch Vaginal Cream

Benzocaine, 5% | Resorcinol, 2%
External Analgesic

Relief from Everyday Itch
Associated with Periods, Clothing, Perspiration

NET WT 1 OZ (28 g)

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Questions and comments? 1-800-351-0177
Weekdays 9:00am - 5:00 pm (EST).

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Essential to Care™ since 1979

 **100% Money Back Guarantee**
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CIN 5442124 REV. 5/19

LEADER REGULAR STRENGTH ANTI-ITCH

benzocaine and resorcinol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0370
Route of Administration	VAGINAL, 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)	
Methylparaben (UNII: A2I8C7HI9T)	
PEG-100 Stearate (UNII: YD01N1999R)	
Propylparaben (UNII: Z8IX2SC1OH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
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:70000-0370-1	1 in 1 CARTON	08/15/2019	
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 not final	part348	08/15/2019	

Labeler - Cardinal Health (097537435)**Establishment**

Name	Address	ID/FEI	Business Operations
Natural Essentials		947484713	MANUFACTURE(70000-0370)

Revised: 8/2019

Cardinal Health