

LEADER MAXIMUM 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 20%

Resorcinol 3%

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

D.

Principal Display Panel - 200 mg Carton Label

LEADER™

NDC 70000-0369-1

Maximum Strength

Anti-Itch

Vaginal Cream

Benzocaine, 20% | Resorcinol, 3%

External Analgesic

LEADERTM

NDC 70000-0369-1

Maximum Strength

Anti-Itch Vaginal Cream

Benzocaine, 20% | Resorcinol, 3%
External Analgesic

LOT
EXP

For Feminine
Itching & Irritation

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

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

100% Money Back Guarantee

NET WT 1 OZ (28g)



CIN 544216 REV. 5/19

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



Return to place of purchase.



DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OHIO 43007
www.myleader.com
1-800-200-6033
Essential CareSM Since 1919

© 2019 Cardinal Health. All rights reserved. CARDINAL HEALTH, the Cardinal Health logo, LEADER, and the Leader logo are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

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

Drug Facts	
Active ingredients Benzocaine 20% Resorcinol 3% External Analgesic	
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, corn oil, disodium EDTA, fragrance, glyceryl stearate, isopropyl myristate, isopropyl palmitate, lanolin, methyl-4-hydroxybenzoate, mineral oil, PEG-100 stearate, propylene glycol, purified water, stearic acid, stearyl alcohol, triethanolamine, vitamin A, E & D.	

LEADERTM

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

Principal Display Panel - 200 mg Vial Label

LEADER™

NDC 70000-0369-1

Maximum Strength

Anti-Itch

Vaginal Cream

Fast, Long-Lasting Relief
from Intense Itch

Associated with Irritating Vaginal Conditions

NET WT 1 OZ (28 g)

NDC 70000-0369-1

LEADER™

Maximum Strength
Anti-Itch Vaginal Cream

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

NET WT 1 OZ (28 g)

Active ingredients: Benzocaine 20%, Resorcinol 3%.
Use: Temporarily relieves itching.
Warnings: For external use only.
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. 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 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: Consult a doctor.
Other information: Store at 20° - 25°C (68° - 77°F).

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

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

© 2019 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health.


DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979


Return to place of purchase.

CIN 5442116 REV. 05/19

LEADER MAXIMUM STRENGTH ANTI-ITCH

benzocaine and resorcinol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0369
Route of Administration	VAGINAL, 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: 2KR89I4H1Y)	
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:70000-0369-1	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(70000-0369)

Revised: 8/2019

Cardinal Health