

VAGI-CURE (REGULAR STRENGTH)- benzocaine, benzalkonium chloride cream
SCI International, Inc. DBA Continental Pharmaceuticals

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.

Directions:

Apply liberally to affected area. If needed may be repeated three to four times daily. Children under (2) two years of age: Consult a physician.

Active ingredients:

Aloe Vera Gel, Carbomer, Cetyl Alcohol, De-ionized Water, Disodium EDTA, Fragrance, Glycerol Monostearate, Isopropyl Myristate, Isopropyl Palmitate, Lanolin Anhydrous, Methylparaben, Mineral Oil, Peg 100 Stearate, propylene Glycol, Propylparaben, Vitamin E (tocopherol)

Warnings:

FOR EXTERNAL USE ONLY. Avoid contact with eyes.

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

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 this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Store at 15 to 30C (49 to 85F)

Manufactured for:

Continental Pharmaceutical Inc.

5904 Enterprise Court

Frederick MD 21703

Web: scimed.com

03-0096

Principal Display Panel – Tube Label

FAST RELIEF from everyday itch!

~Recommended By Women~

Vagi-cure

Anti-Itch Cream

Advanced Sensitive Medicated Cream



Directions: Apply liberally to affected area. If needed may be repeated three to four times daily. Children under (2) two years of age: Consult a physician.

Active ingredients: Benzocaine 5% and Benzalkonium Chloride .13%

Inactive ingredients: Aloe Vera Gel, Carbomer, Cetyl Alcohol, De-ionized Water, Disodium EDTA, Fragrance, Glycerol Monostearate, Isopropyl Myristate, Isopropyl Palmitate, Lanolin Anhydrous, Methylparaben, Mineral Oil, Peg 100 Stearate, Propylene Glycol, Propylparaben, Vitamin E (Tocopherol)

Warnings: FOR EXTERNAL USE ONLY. Avoid contact with eyes. Stop use and ask doctor if condition worsens, or if symptoms persist for more than 7 days, or clear up and occur

again within a few days. 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 this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Vagi-Cure

Anti-Itch Cream



Advanced Sensitive Medicated Cream

NET WT .75oz (21g)

VAGI-CURE (REGULAR STRENGTH)

benzocaine, benzalkonium chloride cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76466-075 |
| 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 |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | .13 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| WATER (UNII: 059QF0K00R) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M) | |
| LANOLIN (UNII: 7EV65EAW6H) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76466-075-07 | 21 g in 1 TUBE; Type 0: Not a Combination Product | 01/01/2011 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 01/01/2011 | |

Labeler - SCI International, Inc. DBA Continental Pharmaceuticals (114220648)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| NATURAL ESSENTIALS, INC. | | 947484713 | MANUFACTURE(76466-075) |

Revised: 1/2018

SCI International, Inc. DBA Continental Pharmaceuticals