# VAGISIL ANTI-ITCH MEDICATED CREME MAXIMUM STRENGTH- benzocaine and resorcinol cream Combe Incorporated

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.

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#### **VAGISIL Anti-Itch Medicated Creme**

### **VAGISIL Maximum Strength Anti-Itch Creme**

**Drug Facts** 

#### **Active ingredient**

Benzocaine 20%

#### Purpose

External analgesic

#### **Active ingredient**

Resorcinol 3%

#### **Purpose**

External analgesic

#### Use

temporarily relieves itching

#### Warnings

#### For external use only

#### **Allergy Allert**

Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other —caine anesthetics.

#### Avoid contact with eyes

in case of contact rinse thoroughly and immediately with water.

#### 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

#### 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-instrip) to affected area not more than 3 to 4 tindaily. Clean nozzle of tube by wiping thoroughly before replacing cap. Keep cap tightly closed between uses.	
children under 12 years	consult a doctor	

#### Other Information:

questions? call 1-800-431-2610, 9 am to 5 pm est

#### **Inactive ingredients**

Water, Mineral Oil, Cetyl Alcohol, Propylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Isopropyl Palmitate, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate, Retinyl Palmitate, Zea Mays (Corn) Oil, Cholecalciferol, Lanolin Alcohol, Fragrance, Methylparaben, Carbomer, Isopropyl Myristate, Isopropyl Stearate, Sodium Sulfite, Triethanolamine, Trisodium HEDTA, Maltodextrin

#### **Principal Display Panel**

Vagisil<sub>®</sub> Maximum Strength Anti-Itch Creme

Net Wt. 1 oz. (28 g)



MAXIMUM STRENGTH ANTI-ITCH CREME NET WIT. 1 OZ. (28 g)	
BLOCK* TECHNOLOGY  PRODUCE IN PH • Initating vaginal conditions  PRODUCK* TECHNOLOGY	
CTAUDIOTIE -	
INSTANT LONG-LASTING ITCH RELIEF STRONGEST MEDICINE* FOR INTENSE ITCH INCLUDING ITCH FROM YEAST INFECTIONS*	TRUSTED BY MORE WOMEN
HTDN STRENGTH	.lisigoVY

## VAGISIL ANTI-ITCH MEDICATED CREME MAXIMUM STRENGTH

benzocaine and resorcinol cream

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11509-4402 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	200 mg in 1 g	
RESORCINOL (UNII: YUL4L094HK) (RESORCINOL - UNII:YUL4L094HK)	RESORCINOL	30 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
MINERAL OIL (UNII: T5L8T28FGP)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4) POLYOXYL 100 STEARATE (UNII: YD01N1999R) ISOPROPYL PALMITATE (UNII: 8 CRQ2TH63M) ALOE VERA LEAF (UNII: ZY81Z83H0X) ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC) CORN OIL (UNII: 8470G57WFM) CHOLECALCIFEROL (UNII: 1C6V77QF41) LANOLIN ALCOHOLS (UNII: 884C3FA9HE) METHYLPARABEN (UNII: A2I8C7HI9T) CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31) ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS) ISOPROPYL STEARATE (UNII: 43253ZW1MZ) **SODIUM SULFITE** (UNII: VTK01UQK3G) TROLAMINE (UNII: 9O3K93S3TK) TRISODIUM HEDTA (UNII: K3E0U7O8KI) MALTO DEXTRIN (UNII: 7CVR7L4A2D)

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packagi	Packaging			
# Iten	n Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:115	509-4402-1	1 in 1 CARTON	03/01/1995	
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	03/01/1995		

# Labeler - Combe Incorporated (002406502)

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