

OMV ANTI-ITCH BIKINI- oatmeal 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.

OMV by Vagisil Bikini Anti-Itch Serum

OMV! by Vagisil™ Bikini Anti-Itch Serum

DRUG FACTS

Active Ingredient

Colloidal Oatmeal 0.01%

Purpose

Skin Protectant

Use

Provides temporary skin protection and relief of minor skin irritation and external itching due to rashes.

Warnings

• **For External Use Only**

• **When using this product**

do not get into 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 in a few days.

• **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to irritated and chafed skin as often as needed for instant relief.

Inactive Ingredients

Water, Cetyl Ethylhexanoate, Glycerin, PEG-40 Hydrogenated Castor Oil, Glyceryl Dilaurate, Phenoxyethanol, Caprylyl Glycol, Sodium Polyacrylate, Dimethicone, Cetareth-20, Glyceryl Oleate, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cyclopentasiloxane, Trideceth-6, Disodium EDTA, Sodium Hydroxide, PEG/PPG-18/18 Dimethicone, Aloe Barbadensis Leaf Extract, Anthemis Nobilis Flower Extract, Tocopheryl Acetate.

PRINCIPAL DISPLAY PANEL

OMV! by Vagisil™ Bikini Anti-Itch Serum

~soothes bikini & intimate area

with colloidal oatmeal

~pH balanced

vanilla clementine

Gynecologist Tested

Net. Wt. 1.7oz (48 g)



OMV ANTI-ITCH BIKINI

oatmeal cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11509-5282

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
WATER (UNII: 059QF0KO0R)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11509-5282-1	1 in 1 CARTON	01/01/2020	
1		48 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	part347	01/01/2020	

Labeler - Combe Incorporated (002406502)