VAGISIL ANTI-ITCH CREME MAXIMUM STRENGTH SENSITIVE SKIN FORMULA- hydrocortisone acetate 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.

Vagisil Anti-Itch Crème Maximum Strength, Sensitive Skin Formula

Vagisil Sensitive Skin Anti-Itch Creme

Drug Facts

Active ingredients

Hydrocortisone Acetate 1%

Purpose

Anti-itch

Use

For temporary external feminine itching.

Warnings

For external use only

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.

Do not use if

you have a vaginal discharge. Consult a physician.

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 to external vaginal area not more than 3 to 4 times a day
children under 12 years	consult a doctor

Inactive ingredients:

water, cetyl ethylhexanoate, glycerin, PEG-40 hydrogenated castor oil, glyceryl dilaurate, dimethicone, colloidal oatmeal, aloe barbadensis leaf extract, sodium polyacrylate, caprylyl glycol, ceteareth-20,

glyceryl oleate, acrylates/C10-30 alkyl acrylate crosspolymer, cyclopentasiloxane, trideceth-6, sodium hydroxide, disodium EDTA, sorbic acid, PEG/PPG-18/18 dimethicone, tocopheryl acetate, maltodextrin, phenoxyethanol.

PRINCIPAL DISPLAY PANEL

Vagisil Sensitive Skin Anti-Itch Creme, 1% Hydrocortisone
Net. Wt. 1 oz. (28 g)

Vagisil.

MAXIMUM STRENGTH FOR SENSITIVE SKIN

#1 GYNECOLOGIST RECOMMENDED INGREDIENT

STOPS ITCH FAST

SENSITIVE HYDROCORTISONE FORMULA

- Stops itch fast & provides long-lasting relief
- Supports healing. Non-greasy, absorbs fast
- Hypoallergenic, non-irritating, no dyes or fragrances

WITH SOOTHING OATMEAL

MEDICATED FORMULA FOR SENSITIVE SKIN TO RELIEVE ITCH ESPECIALLY ASSOCIATED WITH:

- Vaginal skin irritations • Rash

DERMATOLOGIST TESTED CLINICALLY TESTED

Vagisil®

SENSITIVE SKIN

ANTI-ITCH CREME

1% HYDROCORTISONE

NET WT. 1 OZ. (28 g)

FPO

0 00000 00000 0

Vagisil.

SENSITIVE SKIN

ANTI-ITCH CREME

Vagisil.

SENSITIVE SKIN HYDROCORTISONE ANTI-ITCH CREME

STOPS ITCH FAST

Your intimate skin is one of the most delicate areas of your body. Vagisil® Sensitive Skin Hydrocortisone Anti-Itch Creme is specially formulated with gynecologist-recommended hydrocortisone to help heal your most sensitive intimate skin and to relieve itch fast.

- **Stops itch fast and provides long-lasting relief**
- **No dyes or fragrances**
- **Non-irritating, hypoallergenic formula, nourishes skin**
- **Contains soothing oatmeal, Vitamin E and Aloe**
- **Supports natural healing of the body.**
- **Non-greasy, absorbs fast**

Vagisil. | **Shameless** about vaginal health™

For more information, visit us at vagisil.com or call 1-800-431-2610 weekdays 9 AM to 5 PM EST.
Combe Incorporated, White Plains, NY 10604
Made and printed in U.S.A.
Vagisil® and logo are registered trademarks of Combe Incorporated.

0041215(0)

Drug Facts

Active ingredients	*Purpose*
Hydrocortisone Acetate 1%	Anti-itch

Use
- For temporary external feminine itching.

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 a vaginal discharge. Consult a physician.

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 to external vaginal area not more than 3 to 4 times a day
children under 12 years	consult a doctor

Inactive ingredients water, cetyl ethylhexanoate, glycerin, PEG-40 hydrogenated castor oil, glyceryl dilaurate, dimethicone, colloidal oatmeal, aloe barbadensis leaf extract, sodium polyacrylate, caprylyl glycol, ceteareth-20, glyceryl oleate, acrylates/C10-30 alkyl acrylate crosspolymer, cyclopentasiloxane, trideceth-6, sodium hydroxide, disodium EDTA, sorbic acid, PEG/PPG-18/18 dimethicone, tocopheryl acetate, maltodextrin, phenoxyethanol. (RD-005101)

VAGISIL ANTI-ITCH CREME MAXIMUM STRENGTH SENSITIVE SKIN FORMULA

hydrocortisone acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11509-5101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	280 mg in 28 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETYL ETHYLHEXANOATE (UNII: 13464 7WMX4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
GLYCERYL DILAURATE (UNII: MFL3ZIE8SK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OATMEAL (UNII: 8PI54V663Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SORBIC ACID (UNII: X045WJ989B)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11509-5101-1	28 g in 1 CARTON; Type 0: Not a Combination Product	01/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	01/30/2016	

Labeler - Combe Incorporated (002406502)

Revised: 4/2020 Combe Incorporated