VAGISIL ANTI-ITCH MEDICATED WIPES MAXIMUM STRENGTH- pramoxine hydrochloride cloth
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 Medicated Wipes Maximum Strength

VAGISIL Anti-Itch Medicated Wipes

Drug Facts

Active ingredient

Pramoxine hydrochloride 1% (w/w)

Purpose

External analgesic

Use

temporarily relieves 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

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	Unfold towelette and gently pat or wipe external vaginal area from front to back. Use each towelette only once and then throw away. Apply to affected area not more than 3 to 4 times daily. Do not flush.
children under 12 years	consult a doctor

Inactive ingredients

water, polysorbate 20, glycerin, phenoxyethanol, disodium cocoamphodiacetate, TEA-cocoyl

glutamate, ethylparaben, disodium EDTA, methylparaben, fragrance, PEG-7 glyceryl cocoate, aloe barbadensis leaf extract, tocopheryl acetate, maltodextrin

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children under 12 years	consult a doctor

Other information

store at room temperature

discard within 2 months of opening

Inactive ingredients

water, polysorbate 20, glycerin, phenoxyethanol, disodium cocoamphodiacetate, TEA-cocoyl glutamate, ethylparaben, disodium EDTA, methylparaben, fragrance, PEG-7 glyceryl cocoate, aloe

barbadensis leaf extract, tocopheryl acetate, maltodextrin

Principal Display Panel

Maximum Strength
Vagisil®

Medicated Anti-Itch Wipes

Instant Relief From Intense Itch

Gynecologist Tested

Clinically Tested

- **On-the-go relief**
- **With Aloe & Vitamin E**
- **Patented Odor Block Technology**

12 individually wrapped disposable wipes

5 in. x 7.28 in. (12.7 cm x 18.5 cm)

Principal Display Panel

Vagisil®
Maximum Strength

Medicated Anti-Itch Wipes

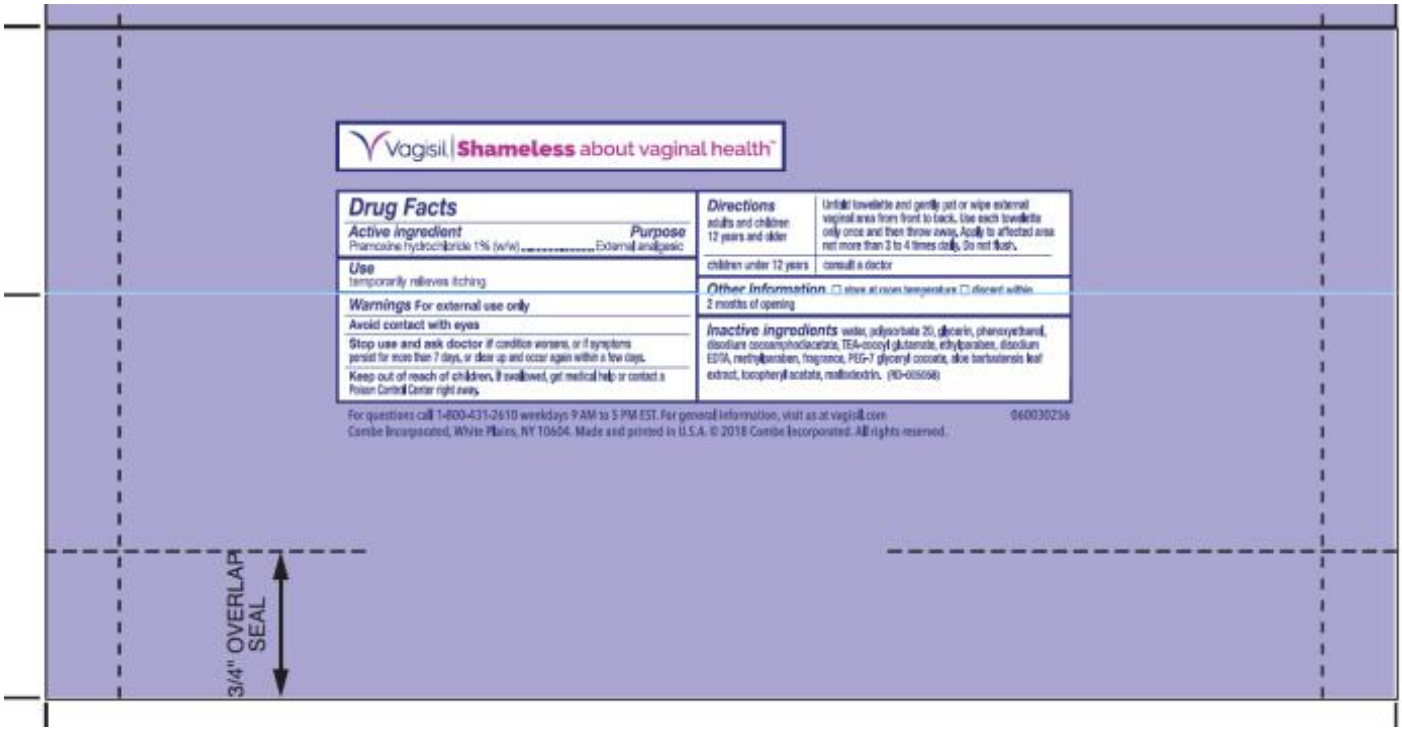
Gynecologist Tested

Instant Relief From Intense Itch

- **With Aloe & Vitamin E**
- **Patented Odor Block Technology**

20 soft, disposable wipes

5 in. x 7.28 in. (12.7 cm x 18.5 cm)



VAGISIL ANTI-ITCH MEDICATED WIPES MAXIMUM STRENGTH

pramoxine hydrochloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11509-5035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
TRIETHANOLAMINE COCOYL GLUTAMATE (UNII: LA19WH54UL)	
ETHYLPARABEN (UNII: 14255EXE39)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11509-5035-1	12 in 1 CARTON	06/28/2005	
1		4.5 g in 1 PACKET; 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	06/28/2005	

VAGISIL ANTI-ITCH MEDICATED WIPES MAXIMUM STRENGTH

pramoxine hydrochloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11509-5058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
TRIETHANOLAMINE COCOYL GLUTAMATE (UNII: LA19WH54UL)	
ETHYLPARABEN (UNII: 14255EXE39)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:11509-5058-1	20 in 1 POUCH	06/28/2005	
1		3.4 g in 1 PACKET; 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	06/28/2005	

Labeler - Combe Incorporated (002406502)

Establishment

Name	Address	ID/FEI	Business Operations
Combe Laboratories, Inc.		808100197	ANALYSIS(11509-5035, 11509-5058) , LABEL(11509-5035, 11509-5058) , MANUFACTURE(11509-5035, 11509-5058) , PACK(11509-5035, 11509-5058)

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