LOLA VAGINAL ITCH RELIEF WIPES- pramoxine hydrochloride cloth
Alyk, Inc.

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.

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

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

- Skin: This product is expected to contact with skin. If irritation is experienced, discontinue use of product. If discomfort persists, seek medical attention.
- Eye: Hold eyelid open and flush with water for at least 15 minutes. If irritation persists, seek medical attention.
- Ingestion: Wipes may present a choking hazard. Accidental ingestion may necessitate medical attention.
- Inhalation: Not likely to be inhaled. If symptomatic, remove to fresh air.

Keep out of reach of children

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 wipe external vaginal area. Use each towelette only once and then throw away. Use no more than 3 to 4 times daily.

Other Information

Use according to package label instructions. Keep in cool storage.

Inactive Ingredient(s)

Aloe Barbadensis Leaf Juice, Avena Sativa (Oat) Bran Extract, Bisabolol, Citric Acid, Decyl Glucoside, Gluconic Acid, Glycerin, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Polyglyceryl-4 Caprate, Polyglyceryl-6 Caprylate, Saccharomyces Ferment Filtrate, Sodium Benzoate, Tetrasodium Glutamate Diacetate, Tocopherol, Vinegar (Apple Cider), Water

Principal Display Panel

LOLA VAGINAL ITCH RELIEF WIPES

pramoxine hydrochloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81032-422

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TOCOPHEROL (UNII: R0ZB2556P8)	
APPLE CIDER VINEGAR (UNII: 0UE22Q87VC)	
WATER (UNII: 059QF0KO0R)	
OAT BRAN (UNII: KQX236OK4U)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
GLUCONIC ACID (UNII: R4R8J0Q44B)	
GLYCERIN (UNII: PDC6A3C0OX)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	
POLYGLYCERYL-4 CAPRATE (UNII: 3N873UN885)	
POLYGLYCERYL-6 CAPRYLATE (UNII: DGV8R54VG7)	
LEVOMENOL (UNII: 24WE03BX2T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81032-422-28	28 in 1 POUCH; Type 0: Not a Combination Product	03/31/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/31/2021	

Labeler - Alyk, Inc. (079830975)

Revised: 4/2021 Alyk, Inc.