HONEY POT- anti-itch soothing liquid Disposable Hygiene LLC dba Anthem

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.

Disposable Hygiene Anti-itching Cream 80 mL

Active Ingredient(s)

Pramoxine hydrochloride 1% (w/w)

Purpose

External analgesic

Use

For temporary relief of pain and itching associated with minor skin irritations.

Warnings

For external use only.

When using this product: avoid contact with eyes.

Stop use and ask a doctor if: • Condition worsens • If symptoms persist for more than 7 days, or clear up and reoccur 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 of age and older: Apply to the affected area not more than 3 or 4 times daily. Children under 12 years of age: Consult a doctor

Inactive ingredients

Water, Polysorbate 20, Glycerin, Pentylene Glycol, Hamamelis virginiana (Witch Hazel) Water, Benzoic Acid, Fragrance, Honey, Vinegar, Aloe Barbadensis Leaf Juice, Sodium Hydroxide, Cucumis Sativus (Cucumber) Fruit Extract, Lavender (Lavandula Angustifolia) Extract, Calendula Officinalis (Calendula) Flower Extract, Cocos Nucifera (Coconut) Fruit Extract, Allium Sativum (Garlic) Extract, Olea Europaea (Olive) Leaf Extract, Potassium Sorbate, Sodium Benzoate, Citric Acid

Other information

Store at a controlled room temperature of 77°F (20-25°C).

For questions and general information visit us at www.thehoneypot.co/contact

Package Label - Principal Display Panel



80 mL NDC: 71505-022-80

HONEY POT

anti-itch soothing liquid

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:71505-022

Route of Administration TOPICAL

Active Ingredient/Active Moiety

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)

Ingredient Name	Basis of Strength	Strength		
	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GARLIC OIL (UNII: 4WG8U28833)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WITCH HAZEL (UNII: 101I4J0U34)	
HONEY (UNII: Y9H1V576FH)	
CUCUMBER FRUIT OIL (UNII: R81Y52NPCT)	
COCONUT OIL (UNII: Q9L0O73W7L)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:71505-022-	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2022	

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

OTC monograph not final	part348	02/15/2022	

Labeler - Disposable Hygiene LLC dba Anthem (079848737)

Establishment			
Name	Address	ID/FEI	Business Operations
Disposable Hygiene LLC dba Anthem		079848737	manufacture(71505-022)

Revised: 2/2022 Disposable Hygiene LLC dba Anthem