REESES PINWORM ITCH RELIEF- pramoxine hydrochloride cloth
Reese Pharmaceutical Co

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.

Reeses PINWORM Itch Relief - Drug Facts Label

Active ingredient

Pramoxine Hydrochloride 1.0% w/w

Purpose

ANALGESIC

Uses

- Temporarily relieves itching

Warnings

For external use only

When using this product

- Avoid contact with eyes

Stop use and ask a doctor if

- Condition worsens or does not improve within 7 days or clears up and reoccurs within a few days

Keep out of the reach of children.

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

Direction

- Adults: unfold wipe and cleanse the area by gently wiping or patting external area from front to back. Use each wipe only once and discard.
- Use up to 5 times daily.
- Children under 12: consult a doctor

Other information

- Store at room temperature
- Discard within 2 months of opening

Inactive ingredients

purified water, glycerin, propylene glycol, cocoamphodiacetate, polysorbate 20, aloe vera barbadensis leaf juice, citric acid, fragrance, diazolidinyl urea, iodopropynyl butylcarbamate.

Questions or comments?

1-800-321-7178

Images of representative packaging

REESES PINWORM ITCH RELIEF

pramoxine hydrochloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10956-799
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)	
GLYCERIN (UNII: PDC6A3C0OX)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-799-20	89 g in 1 PACKAGE; Type 0: Not a Combination Product	10/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/21/2013	

Labeler - Reese Pharmaceutical Co (004172052)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Guy & O'Neill, Inc.		138513069	manufacture(10956-799) , label(10956-799)

Revised: 10/2017 Reese Pharmaceutical Co