REXALL MAXIMUM STRENGTH HEMORRHOIDAL - pramoxine hydrochloride, glycerin, phenylephrine hydrochloride and petrolatum cream
Dolgencorp, 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.

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drug facts

Active ingredients	**Purpose**
Glycerin 14.4%	Protectant
Petrolatum 15%	Protectant
Phenylephrine Hydrochloride 0.25%	Vasoconstrictor
Pramoxine HCl 1%	Local anesthetic

Uses

- for temporary relief of pain, soreness and burning
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Other information

- store at 20 degrees - 25 degrees C (68 degrees - 77 degrees F)
- for lot number and expiration date, see crimp of tube or see box

Warnings

For external use only.

Ask a doctor before use if you have

- heart disease - high blood pressure - thyroid disease - diabetes

- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put into rectum by using fingers or any mechanical device or applicator
- use only the provided dispensing cap

Stop use and ask a doctor if
- bleeding occurs
- condition worsens or does not improve within 7 days
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase

If pregnant or breast feeding, ask a health professional before use.

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Directions

- **adults:**when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or soft cloth before applying cream.
- When first opening the tube, puncture foil seal with top end of cap.
- apply externally or in the lower portion of the anal canal only
- apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert cap partway into the anus.
- thoroughly cleanse dispensing cap after each use and replace cover
- **children under 12 years of age:** ask a doctor

Inactive Ingredients aloe barbadensis leaf juice, butylated hydroxyanisole, cellulose gum, cetyl alcohol, citric acid, disodium EDTA, glyceryl stearate SE, laureth-23, methylparaben, mineral oil, penthenol, propylene glycol, propyl gallate, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, tocopheryl acetate, xanthan gum

Rexall®
Since 1903

NET WT 1.0 OZ (28g)

Hemorrhoidal Cream

MAXIMUM STRENGTH

- Rapid, soothing pain relief from burning, itching and discomfort
- Protects irritated tissue

BX142DG1OZ-1

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30890
P032-0124-00-RT
SEABOARD FOLDING BOX CORPORATION

QUALITY SEALED TUBE FOR YOUR PROTECTION. DO NOT USE IF TUBE SEAL UNDER CAP IS MISSING OR BROKEN

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Drug Facts (continued)

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Inactive ingredients

aloe barbadensis leaf juice, butylated hydroxyanisole, cellulose gum, cetyl alcohol, citric acid, disodium EDTA, glyceryl stearate SE, laureth-23, methylparaben, mineral oil, panthenol, propylene glycol, propyl gallate, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, tocopheryl acetate, xanthan gum

*This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Preparation H® Hemorrhoidal Cream®

Visit us at:
Rexall.com or call
1-866-4-REXALL

PACKAGED FOR DOLGENCORP, LLC
100 MISSION RIDGE, GOODLETTSVILLE, TN
37072 USA

REXALL MAXIMUM STRENGTH HEMORRHOIDAL

pramoxine hydrochloride, glycerin, phenylephrine hydrochloride and petrolatum cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-402
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
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
LAURETH-23 (UNII: N72LMW566G)	
MINERAL OIL (UNII: T5L8T28FGP)	
PANTHENOL (UNII: WV9CM0O67Z)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55910-402-03	1 in 1 CARTON		

1		28 g in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	06/28/2011	

Labeler - Dolgencorp, Inc. (068331990)

Registrant - Pharma Pac, LLC (140807475)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

Revised: 6/2011 Dolgencorp, Inc.