## MAKESENSE - phenylephrine hydrochloride zinc oxide cream Cherry Hill Sales 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.

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## **Drug Facts**

## **Active Ingredient**

Phenylephrine HCL 0.25% Zinc Oxide 12.50%

#### **Purpose**

Vasoconstrictor

Astringent

#### Uses

For temporary relief of local anorectal burning and discomfort associated with hemorrhoids, anorectal disorders, inflamed hemorrhoidal tissues or piles.

## Warnings

### For external use only

#### Do not use

■ on children under 2 years of age except under the advise and supervision of a doctor ■ for diaper rash

#### Stop use and ask a doctor if

■ condition worsens or symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days ■ Do not exceed the recomended daily dosage unless directed by a doctor ■ In case of bleeding, consult a doctor promptly ■ Certain persons can develop allergic reactions to ingredients in this product ■ If the symptom treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult doctor ■ If you are pregnant, do not use this product without first consulting doctor.

# Keep out of reach of children

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

#### **Directions**

■ Cleanse affected area with mild soap and warm water, rinse thoroubly ■ Dry by patting or blotting with toilet tissue

or soft cloth before applying ■ Cover the entire affected area with a thin layer 1 to 3 times daily ■ Children under 12 years of age need

to consult doctor before using this product

# Other information

■ store at 68-77F (20 to 25C) ■ See Lot No. and Exp. Date: on box and crimp of tube

# **Inactive Ingredients**

Lanolin, Methylparaben, Ozokerite, Paraffin, Propylparaben, White Petrolatum

# Package Label



## **MAKESENSE**

phenylephrine hydrochloride zinc oxide cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69020-205	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	12.5 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
CERESIN (UNII: Q1LS2UJO3A)			
LANOLIN (UNII: 7EV65EAW6H)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			
PARAFFIN (UNII: 1900E3H2ZE)			
PETROLATUM (UNII: 4T6H12BN9U)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			

ı	Packaging	ckaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:69020-205-28	28 g in 1 TUBE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part346	07/31/2014			

# Labeler - Cherry Hill Sales Co (145959768)

Revised: 8/2014 Cherry Hill Sales Co