PURTECT - petrolatum, chloroxylenol ointment PurKlenz Formulations 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 Ingredients

Drug Facts

Active ingredients

Petrolatum 63% Chloroxylenol 0.8%

Purpose

Purpose

Skin Protectant Antiseptic

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.

Uses

Uses

Temporarily protects:

- minor cuts, scrapes and burns
- temporarily protects and helps relieve chafed or cracked skin
- help protects from the drying effects of wind and cold weather

Warnings

Warnings

- For external use only
- do not get near eyes

Do not use on

- deep puncture wounds
- animal bites
- serious burns

Do not use if you are allergic to any ingredients listed Stop use and ask a doctor if

- condition worsens
- irritation, rash or other allergic reaction develops

Directions

Directions

- Thoroughly clean affected area and allow to dry
- Apply ointment sparingly on affected area as needed

Other Information

Other information

- Reseal container after use
- Avoid freezing
- Store between 4 degrees and 30 degrees C (40 degrees and 86 degrees F)
- See tube crimp for lot number and expiration date

Inactive Ingredients

Inactive Ingredients: Paraffium Liquidum, Paraffin, Propylene Glycol, Tocopheryl Acetate, Squalane, Retinyl Palmitate, Cocos Nucifera (Coconut) Oil, Aloe Barbadensis Leaf Extract

Package Label

PurTect

Topical Ointment and Skin Protectant

Helps protect the Skin's Moisture Barrier

Enriched with Vitamins A and E

Helps Prevent Damage Caused by Dryness

4 Fl. Oz (118 mL)

NDC 49436-xxx-xx

Made in Canada Distributed in the U.S.A. by PurKlenz Formulations Inc.

Questions or comments? www.purklenz.com



Topical Ointment & Skin Protectant

Helps protect the Skin's Moisture Barrier Enriched with Vitamins A & E Helps Prevent Damage Caused by Dryness

NDC 49436-290-01

4 Oz. (118 mL)

Drug Facts

Active ingredients: Purpose:

Petrolatum 63%.....Skin Protectant

Chloroxylenol 0.8%..... Antiseptic

Uses:

Temporarily protects:

- minor cuts, scrapes & burns
- temporarily protects and helps relieve chafed or cracked skin
- helps protect from the drying effects of wind and cold weather

Warnings:

- · For external use only
- do not get in or near eyes

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Do not use if you are allergic to any of the ingredients listed Stop use and ask a doctor if

- condition worsens
- irritation, rash or other allergic reaction develops

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

Directions:

- Thoroughly clean affected area and allow to dry
- Apply ointment sparingly on affected area as needed

Other information:

- Reseal container after use
- Avoid freezing
- Store between 4°and 30°C (40° and 86°F)
- See tube crimp for lot number and expiration date

Inactive Ingredients: Paraffinum Liquidum, Paraffin, Propylene Glycol, Tocopheryl Acetate, Squalane, Retinyl Palmitate, Cocos Nucifera (Coconut) Oil, Aloe Barbadensis Leaf Extract

PURTECT

petrolatum, chloroxylenol ointment

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TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	63 mL in 100 mL		
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.8 mL in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
MINERAL OIL (UNII: T5L8T28FGP)			
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
SQUALANE (UNII: GW89575KF9)			
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)			
COCONUT OIL (UNII: Q9L0O73W7L)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49436-290-01	118 mL in 1 TUBE				
2	NDC:49436-290-02	20 mL in 1 TUBE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	05/01/2012		

Labeler - PurKlenz Formulations Inc. (078444179)

Registrant - PurKlenz Formulations Inc. (078444179)

Revised: 5/2012 PurKlenz Formulations Inc.