

ROYAL PETROLEUM (COCOA SCENT)- petrolatum jelly

Filo America

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.

Drug Fact

Creamy petroleum Jelly is specially formulated to moisturize, soften and soothe dry skin. Blended with Vitamin E to produce a rich creamy moisturizer. Use on hands, knees, feet and heels to smooth away dryness. Great for moisturizing face and neck.

DRUG FACTS

Active Ingredient	Purpose
Petrolatum 30%	Skin Protectant

Purpose

Skin Protectant

Temporarily protects minor: cuts scrapes burns

Temporarily protects and helps relieve chapped or cracked skin

Helps protect from the drying effects of wind and cold weather

Warnings

For external use only. Do not use on deep puncture wounds.

When using this product, do not get into eyes

Stop use and ask doctor if condition worsens, Symptoms last more than 7 days clear up and occur 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: apply as needed

Inactive ingredients:

water (Aqua), Carbopol 940, Stearic Acid, Glyceryl Monostearate, Mineral Oil, Cetearyl Alcohol, GE125 Emulsifying Agent, Methylparaben, Propylparaben, Triethanolamine, Tocopheryl Acetate, Cocoa Butter, Fragrance.

*This product is not manufactured or distributed by Unilever, distributor of the registered trademark Vaseline (r)

MADE IN CHINA

DISTRIBUTED BY:

Filo America

P.O. Box 23592

Los Angeles, CA 90023

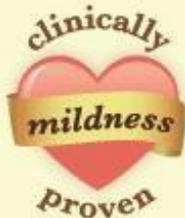
Questions or Concerns?

1.866.460.0322



Cocoa Scent

Creamy Petroleum Jelly



Skin Protectant

Non-Greasy Rich, Soothing Texture Compare to the active ingredients in Vaseline®

NET WT 7 OZ (198g)

21mm

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Drug Facts

Active Ingredient: Petrolatum 30% Purpose: Skin Protectant

Uses:

- Temporarily protects minor cuts, scrapes, burns
Temporarily protects and helps relieve chapped or cracked skin
Helps protect from the drying effects of wind and cold weather

Warnings:

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Stop use and ask doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.
Do not use on deep puncture wounds. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Apply as needed.

Inactive Ingredients: Water (Aqua), Carbopol 940, Stearic Acid, Glyceryl Monostearate, Mineral Oil, Cetearyl Alcohol, GEl25 Emulsifying Agent, Methylparaben, Propylparaben, Triethanolamine, Tocopheryl Acetate, Fragrance.

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ROYAL PETROLEUM (COCOA SCENT)

petrolatum jelly

Product Information

Table with 4 columns: Product Type (HUMAN OTC DRUG), Item Code (Source) (NDC:50438-400), Route of Administration (TOPICAL)

Active Ingredient/Active Moiety

Table with 3 columns: Ingredient Name (PETROLATUM), Basis of Strength (PETROLATUM), Strength (30 g in 100 g)

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-400-01	198 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/19/2014	

Labeler - Filo America (943873703)

Registrant - NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD. (529047265)

Establishment

Name	Address	ID/FEI	Business Operations
NINGBO PULISI DAILY CHEMICAL PRODUCTS CO., LTD.		529047265	manufacture(50438-400)

Revised: 2/2014

Filo America