PETROLATUM- petrolatum cream Greenbrier International, 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.

ASSURED™ Drug Facts

Active Ingredient:

White Petrolatum USP (30 %)

Purpose

Skin protectant

Uses

- temporarily protects minor:
 - o 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, animal bites and serious burns.

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), glycerin, glyceryl monostearate, PEG-100 stearate, stearic acid, ceteareth 20, trieathanolamine, lanolin alcohol, fragrance, acrylates/C 10-30 alkyl acrylate crosspolymer, phenoxyethanol, triethylene glycol, cocoa butter, tocopheryl acetate, disodium EDTA

110781 DISTRIBUTED BY

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY,

CHESAPEAKE, VA 23320

MADE IN INDIA

Skin Softener

Hydrates &

Evens Skin Tone

COCOA

BUTTER

Petroleum Jelly

C. No. DNH/COS/DNH/130

1222101976

Principal Display Panel - 3 oz Tube Label

ASSUREDTM

Vitamin E Enriched

Creamy

COCOA

BUTTER

Petroleum Jelly

Skin Softener

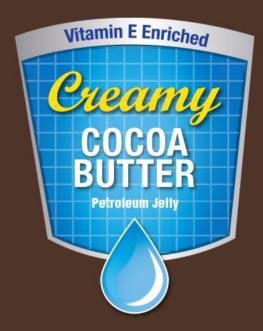
Hydrates &

Evens Skin Tone

Net Wt 3 oz (85g)

NDC # 33992-0498-1

ASSURE



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ASSURE

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PETROLATUM

petrolatum cream

Product Information

HUMAN OTC DRUG NDC:33992-0498 Product Type Item Code (Source)

Route of Administration **TOPICAL**

Active Ingredient/Active Moiety

Active ingredictionactive wholety				
Ingredient Name	Basis of Strength	Strength		
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Pe tro la tum	30 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
PEG-100 STEARATE (UNII: YD01N1999R)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528 SWUY)			
TROLAMINE (UNII: 9O3K93S3TK)			
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)			
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
TRIETHYLENE GLYCOL (UNII: 3P5SU53360)			
COCOA BUTTER (UNII: 512OYT1CRR)			
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			

	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:33992-0498-1	85 g in 1 TUBE; Type 0: Not a Combination Product	05/17/2019		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	05/17/2019		

$\boldsymbol{Labeler} \text{ - } \textbf{Greenbrier International, Inc. (610322518)}$

Revised: 5/2019 Greenbrier International, Inc.