

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:
 - 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, cetareth 20, triethanolamine, 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

ASSURED™

Vitamin E Enriched

Creamy

COCOA

BUTTER

Petroleum Jelly

Skin Softener

**Hydrates &
Evens Skin Tone**

Net Wt 3 oz (85g)

NDC # 33992-0498-1

ASSURED™



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PETROLATUM

petrolatum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0498
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
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)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

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	

Labeler - Greenbrier International, Inc. (610322518)

Revised: 5/2019

Greenbrier International, Inc.