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.

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

Principal Display Panel - Petroleum Jelly Tube Label

 $\mathbf{ASSURED}^{\mathsf{TM}}$

Vitamin E Enriched

Creamy PETROLEUM JELLY

Skin Softener

For Dry Skin

Absorbs Quickly

Compare to active ingredient of Vas eline $^{\mathbb{R}}$ Deep Mois ture $^{\text{TM}}$

Net Wt 3 oz (85g)

NDC # 33992-0499-1





Skin Softener For Dry Skin **Absorbs Quickly**

Compare to active ingredient of Vaseline® Deep Moisture™*

Net Wt 3 oz (85g)

NDC # 33992-0499-1

ASSURED 5

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.

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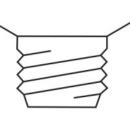
Directions apply as needed.

Inactive ingredients water (aqua), glycerine, glyceryl monostearate, PEG 100 stearate, stearic acid, ceteareth 20, triethanolamine, lanolin alcohol, fragrance, acrylates/C 10-30 alkyl acrylate crosspolymer, phenoxyethanol, triethylene glycol, tocopheryl acetate, disodium EDTA



989481 DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC. 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320 MADE IN INDIA

> C. No. DNH/COS/DNH/130 1222101977



PETROLATUM

petrolatum cream

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:33992-0499 |
|-------------------------|----------------|--------------------|----------------|
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|---------------|--|
| 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 OU9 XXE4) | | |
| 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) | | |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) | | |
| EDETATE DISO DIUM (UNII: 7FLD91C86K) | | |

|] | Packaging | | | | |
|---|------------------|---|-----------------------------|---------------------------|--|
| 7 | # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | NDC:33992-0499-1 | 85 g in 1 TUBE; Type 0: Not a Combination Product | 02/04/2019 | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part347 | 02/04/2019 | | |
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Labeler - Greenbrier International, Inc. (610322518)

Revised: 2/2019 Greenbrier International, Inc.