

**UNIVERSAL PURE PETROLEUM COCOA BUTTER SCENTED- white
petroleum jelly
Universal Distribution Center LLC**

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 ingredient

White Petrolatum USP (100 %)

Purpose

Skin Protectant

Uses

- For the temporary protection of minor cuts, scrapes, burns and sunburn.
- Helps to temporarily protect chafed, chapped, cracked or windburned skin and lips.

Warnings

For External Use Only.

Do not use over deep or puncture wounds, infections or lacerations. Ask a doctor.

When using this product avoid contact with eyes.

Stop use and ask doctor if condition worsens or does not improve within 7 days.

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

Directions

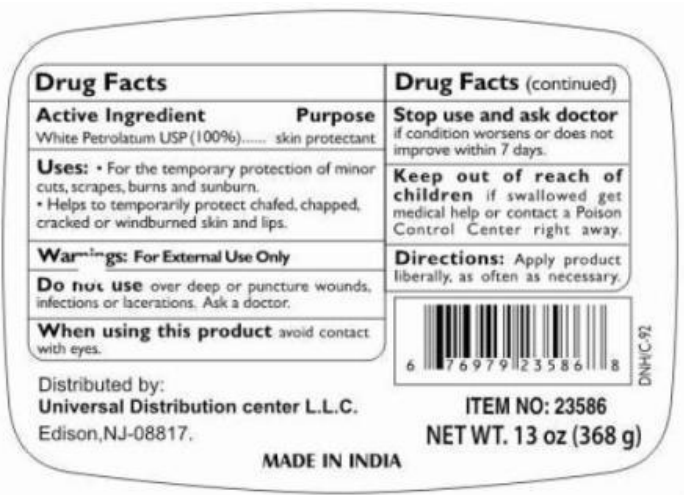
Apply product as liberally, as often as necessary.

Inactive ingredients

None

PRINCIPAL DISPLAY PANEL

UNIVERSAL PURE PETROLEUM COCOA BUTTER SCENTED JELLY
SKIN PROTECTANT
NET WT. 13 OZ (368 g)



UNIVERSAL PURE PETROLEUM COCOA BUTTER SCENTED

white petroleum jelly

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52000-007 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------|
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 1 g in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | 0.0001 g in 1 g |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52000-007-19 | 226 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 2 | NDC:52000-007-20 | 45 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 3 | NDC:52000-007-21 | 100 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 4 | NDC:52000-007-22 | 113 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 5 | NDC:52000-007-23 | 170 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 6 | NDC:52000-007-24 | 198 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 7 | NDC:52000-007-25 | 283 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |

| | | | | |
|----|------------------|---|------------|--|
| 8 | NDC:52000-007-26 | 368 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 9 | NDC:52000-007-27 | 450 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |
| 10 | NDC:52000-007-28 | 500 g in 1 JAR; Type 0: Not a Combination Product | 03/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 02/06/2013 | |

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|------------------------|
| Jell Pharmaceuticals Pvt. Ltd. | | 726025211 | manufacture(52000-007) |

Revised: 10/2022

Universal Distribution Center LLC