

**YOURS BABY FRESH SCENT PETROLEUM- white petrolatum jelly
TRANSWORLD INTERNATIONAL TRADING CORP.**

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.

Yours Baby Fresh Scent Petroleum Jelly

Active Ingredient

White Petrolatum USP (99.9%)

Purpose

Skin Protectant

Uses

- Yours Petroleum Jelly is ideal for your baby's skin care needs.
- Restores smooth and healthy skin.
- Helps to treat and prevent your baby's delicate skin from diaper rash.
- It works to seal out wetness.
- Helps to soothe dry, chapped, cracked or irritated skin and lips due to cold and wind.

Warnings

For External Use Only.

When using this product

- Avoid contact with eyes.

Stop use and ask a doctor

- If condition worsens or does not improve after 7 days.

Keep out of reach of children

- If swallowed get medical help or contact a Poison Control Center right away.

Directions

Cleanse and dry area, apply liberally, as often as necessary.

Inactive Ingredient

Fragrance

PRINCIPAL DISPLAY PANEL

YOURS BABY FRESH SCENT PETROLEUM JELLY

NET WT. 8OZ. (226 g)



YOURS BABY FRESH SCENT PETROLEUM

white petrolatum jelly

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71265-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 99.9 g in 100 g |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71265-002-01 | 50 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 2 | NDC:71265-002-03 | 113 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 3 | NDC:71265-002-04 | 170 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 4 | NDC:71265-002-05 | 226 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 5 | NDC:71265-002-06 | 283 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 6 | NDC:71265-002-07 | 368 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 7 | NDC:71265-002-08 | 425 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 8 | NDC:71265-002-09 | 450 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |
| 9 | NDC:71265-002-10 | 500 g in 1 JAR; Type 0: Not a Combination Product | 03/02/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 03/02/2017 | |

Labeler - TRANSWORLD INTERNATIONAL TRADING CORP. (135417736)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|------------------------|
| Jell Pharmaceuticals Pvt. Ltd. | | 726025211 | manufacture(71265-002) |

Revised: 3/2017

TRANSWORLD INTERNATIONAL TRADING CORP.