

KROGER LIP TREATMENT- petrolatum gel

Kroger

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

Petrolatum, 100%

Purpose

Skin Protectant

Keep Out of Reach of Children

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

Uses

Temporarily protects chapped or cracked lips. Helps protect lips from drying effects of wind and cold weather.

Warnings

For external use only. When using this product –Do not get into eyes. Stop use and ask a doctor if – condition worsens-symptoms last more than 7 days or clear up and occur again within a few days.

Directions

Apply as needed.

Inactive Ingredients

Flavor

Package/Label Principal Display Panel



KROGER LIP TREATMENT

petrolatum gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:30 142-930 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 99.98 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) | 0.02 mg in 1 g |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|---------------------|----------------------|--------------------|
| 1 | NDC:30 142-930-03 | 1 g in 1 TUBE | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part347 | 05/02/2013 | |

Labeler - Kroger (006999528)

Registrant - OraLabs (801824756)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------|---------|-----------|---|
| OraLabs | | 801824756 | MANUFACTURE(30 142-930) , LABEL(30 142-930) |

Revised: 4/2013

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