D-CERIN- moisturizer cream Dynarex Corporation

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.

1473 D-Cerin, NDC 67777-147-30

Active ingredient

Petrolatum 33%

Purpose

Skin Protectant

Uses

- Temporarily protects and helps relieve dry, chapped, or cracked skin
- Helps protect skin from the drying effects of wind and cold weather

Warnings

For External Use Only

Avoid contact with eyes.

In case of contact, flush thoroughly with water.

Stop use and ask a doctor if

- conditions worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Do not use

on deep puncture wounds, animal bites, or serious burns.

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

Directions

Apply as needed or as directed by a physician.

Other information

Store at room temperature (59° - 86°F).

Inactive Ingredients

DMDM Hydantoin, Lanolin Alcohol, Methyl Paraben, Mineral Oil, Paraffin, PEG 30 Dipolyhydroxystearate, Propylene Glycol, Propylparaben, Purified Water, Sodium Chloride

Questions?

Label



D-CERIN

ADVANCED MOISTURIZING CREAM

3.75 oz. (106 g)

Drug Facts

Active ingredient

Purpose

Petrolatum 33% Skin Protectant

- Temporarily protects and helps relieve dry, chapped, or cracked skin
- Helps protect skin from the drying effects of wind and cold weather

Warnings

For External Use Only

Avoid contact with eyes. In case of contact, flush thoroughly with water.

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

Do not use on deep puncture wounds, animal bites, or serious burns.

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

Directions

Apply as needed or as directed by a physician.

Other information

Store at room temperature (59°- 86°F).

Inactive ingredients

DMDM Hydantoin, Lanolin Alcohol, Methyl Paraben, Mineral Oil, Paraffin, PEG 30 Dipolyhydroxystearate, Propylene Glycol, Propylparaben, Purified Water, Sodium Chloride

Questions?

1-888-DYNAREX Monday-Friday, 9AM-5PM EST



R190107

Reorder No. 1473

Manufactured for: **Dynarex Corporation** 10 Glenshaw Street Orangeburg, NY 10962 USA · www.dynarex.com

Made in India



SYMBOL GLOSSARY For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php



D-CERIN

moisturizer cream

Product Information

HUMAN OTC DRUG Product Type

TOPICAL Route of Administration

Item Code (Source)

NDC:67777-147

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|---------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 33 g in 100 g | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| WATER (UNII: 059QF0KO0R) | |
| PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E) | |
| PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO) | |
| LANOLIN ALCOHOLS (UNII: 884C3FA9HE) | |
| DMDM HYDANTO IN (UNII: BYR0546 TOW) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| METHYLPARABEN (UNII: A2I8 C7HI9 T) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

| Packaging | | | | |
|--------------------|--|-----------------------------|---------------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 NDC:67777-147-30 | 24 in 1 CASE | 08/20/2018 | | |
| 1 | 111 g in 1 TUBE; Type 0: Not a Combination Product | | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part347 | 08/20/2018 | | |
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Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 1/2019 Dynarex Corporation