

HAND ESSENTIALS SKIN REPAIR- dimethicone cream
HU-FRIEDY MFG. CO., 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

Dimethicone 1.5%

Purpose

Skin protectant

Uses

- Temporarily protects and helps relieve chapped or cracked skin. Beneficial for face, hands, body and legs.

Warnings

For External Use Only.

Do not use

- on deep or puncture wounds
- on animal bites
- on serious burns

When using this product

- do not get into eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or 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 cream liberally as needed.

Other information

- Protect from freezing. Avoid excessive heat.

Inactive ingredients

Aloe Barbadensis Leaf Juice, Ascorbic Acid, Ascorbyl Palmitate, Canola Oil, Cetyl Alcohol, Cholecalciferol, Citric Acid, Citrus Aurantium Dulcis Peel Oil, Citrus Grandis Peel Oil, Citrus Tangerina Peel Oil, Diazolidinyl Urea, Glycerin, Glyceryl Stearate SE, Glycine, Hydroxytyrosol, L-

proline, L-taurine, Methylparaben, Methylsulfonylmethane, N-acetyl-L-cysteine, Niacinamide, Olea Europaea Fruit Oil, PEG-8, PEG-100 Stearate, Propylene Glycol, Propylparaben, Pyridoxine HCl, Retinyl Palmitate, Stearic Acid, Stearyl Alcohol, Tetrasodium EDTA, Tocopherol, Triethanolamine, Vanillin, Water, Zea Mays Oil.

Package/Label Principal Display Panel

+D671792217B

*Hu-Friedy Hand Essentials with nourishing Olivamine®:
A blend of potent antioxidants, amino acids, vitamins & MSM.*

| Drug Facts | |
|---|---|
| <i>Active ingredient</i> | <i>Purpose</i> |
| Dimethicone 15%..... | Skin Protectant |
| Uses ■ Temporarily protects and helps relieve chapped or cracked skin. Beneficial for face, hands, body and legs. | |
| Warnings | |
| For External Use Only | |
| Do not use ■ on deep or puncture wounds ■ on animal bites ■ on serious burns. | |
| When using this product ■ do not get into eyes. | |
| Stop use and ask a doctor if ■ condition worsens ■ symptoms last for more than 7 days or 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 cream liberally as needed. | |
| Other information ■ Protect from freezing. Avoid excessive heat. | |
| Inactive ingredients Aloe Barbadensis Leaf Juice, Ascorbic Acid, Ascorbyl Palmitate, Canola Oil, Cetyl Alcohol, Cholecalciferol, Citric Acid, Citrus Aurantium Dulcis Peel Oil, Citrus Grandis Peel Oil, Citrus Tangerina Peel Oil, Diazolidinyl Urea, Glycerin, Glyceryl Stearate SE, Glycine, Hydroxytyrosol, L-proline, L-taurine, Methylparaben, Methylsulfonylmethane, N-acetyl-L-cysteine, Niacinamide, Olea Europaea Fruit Oil, PEG-8, PEG-100 Stearate, Propylene Glycol, Propylparaben, Pyridoxine HCl, Retinyl Palmitate, Stearic Acid, Stearyl Alcohol, Tetrasodium EDTA, Tocopherol, Triethanolamine, Vanillin, Water, Zea Mays Oil. | |
| Manufactured for: Hu-Friedy Mfg. Co., LLC 3232 N. Rockwell St. Chicago, IL 60618 1-800-Hu-Friedy · Hu-Friedy.com | |
| REORDER: IMS-1502 |    |
| MADE IN USA | M1000/0810 |

Hu-Friedy
HAND ESSENTIALS™
Skin Repair Cream

*Every Day Moisturizer
with Olivamine®*

- Nourishes & conditions dry, cracked skin
- Non-allergenic
- Non-sensitizing
- CHG & latex friendly

Part-code: IMS-1502

Hu-Friedy®

2 Fl oz (59 mL)

A Medline Remedy® Product. Medline Remedy is a registered trademark of Medline Industries, Inc. Olivamine is a registered trademark of McCord Research, Inc.

Hu-Friedy

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2 Fl oz (59 mL)

HAND ESSENTIALS SKIN REPAIR

dimethicone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65626-161 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|------------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 1.5 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| CANOLA OIL (UNII: 331KBJ17RK) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ORANGE OIL (UNII: AKN3KSD11B) | |
| MANDARIN OIL (UNII: NJO720F72R) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| GLYCINE (UNII: TE7660XO1C) | |
| PROLINE (UNII: 9DLQ4CIU6V) | |
| TAURINE (UNII: 1EQV5MLY3D) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) | |
| ACETYLCYSTEINE (UNII: WYQ7N0BPYC) | |
| NIACINAMIDE (UNII: 25X51I8RD4) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |

| | |
|--|--|
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| VANILLIN (UNII: CH1530446X) | |
| WATER (UNII: 059QF0K00R) | |
| CORN OIL (UNII: 8470G57WFM) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------|----------------------|--------------------|
| 1 | NDC:65626-161-23 | 946 mL in 1 BOTTLE, PUMP | | |
| 2 | NDC:65626-161-13 | 59 mL in 1 TUBE | | |
| 3 | NDC:65626-161-04 | 118 mL in 1 TUBE | | |
| 4 | NDC:65626-161-96 | 144 in 1 CARTON | | |
| 4 | | 4 mL in 1 PACKET | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 10/01/2010 | |

Labeler - HU-FRIEDY MFG. CO., INC. (005085972)

Revised: 3/2012

HU-FRIEDY MFG. CO., INC.