

MEDLINE- zinc oxide, petrolatum cream
Medline Industries, LP

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.

176 Curad Zinc Oxide Cream CUR009814

Active ingredients (in each gram)

- White petrolatum 78% w/w, USP
- Zinc oxide 20% w/w, USP

Purpose

- Skin protectant

Uses

- temporarily protects minor cuts, scrapes and burns
- helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin
- helps treat and prevent diaper rash. Protects minor skin irritation associated with diaper rash and helps seal out wetness

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

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children.

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

Directions

- for skin protection: apply as needed

- for diaper rash: change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry
- apply cream liberally, as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged

Other information

- store at controlled room temperature 68-77°F (20-25°C)
- use only if packaging is intact

Inactive ingredients

cetostearyl alcohol, light mineral oil, macrogol cetostearyl ether 20

Manufacturing information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

www.curad.com

1-800-633-5463

Made in India

REF: CUR009814

V2 RA23GZP

53329-176-14 Package Label



NDC: 53329-176-14

ZINC OXIDE 20% CREAM

SKIN PROTECTANT

REF **CUR009814**

Not made with natural rubber latex.

NET WT. 2 oz (56.6 g)



Family-owned.
Trusted by hospitals
for over 50 years.

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Drug Facts

| | |
|--|-----------------|
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Drug Facts (continued)

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MEDLINE

zinc oxide, petrolatum cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53329-176 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 20 g in 100 g |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 78 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| | | | | |
|------------------------------|---|---|-----------------------------|---------------------------|
| 1 | NDC:53329-176-14 | 57 g in 1 TUBE; Type 0: Not a Combination Product | 04/01/2023 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| OTC monograph final | M016 | | 04/01/2023 | |

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 6/2023

Medline Industries, LP