

MEDPRIDE EN SHIELD ALOE SOFT VITAMIN ENRICHED- zinc oxide cream
Shield Line LLC

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

Zinc Oxide (1.8%w/w)

Purpose

Skin Protectant

Uses

■ helps treat and prevent diaper rash ■ temporarily protects minor ■ cuts ■ scrapes ■ burns dries the oozing and weeping of: ■ Poison ivy ■ poison oak ■ poison sumac

Warnings

For external use only

When using this product

■ do not get into eyes

Stop Use and ask a doctor if

if conditions worsen symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

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

Directions

■ change wet and soiled diapers promptly ■ cleanse the diaper area and allow to dry ■ apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged ■ for poison ivy, oak and sumac ■ apply ointment liberally as needed

Other Information


■ store at room temperature 15-30C (59-86F) ■ avoid excessive heat

Inactive ingredients

aloe vera leaf, alpha-tocopherol, aeteth-10, cetostearyl alcohol, cetyl alcohol, cholecalciferol, glycerin, lanolin, lavender methylparaben, mineral oil, paraffin, petrolatum, phenoxyethanol, polyethylene glycol 6000,

polysorbate 60, propylparaben sodium steareth-20, trolamine, vitamin A, water, FDC Yellow No.5, DC Red No.21

Package Label



En-Shield
SKIN PROTECTANT
ALOE SOFT • VITAMIN ENRICHED

VITAMIN A • VITAMIN D • VITAMIN E
ZINC OXIDE • ALOE VERA

Net Wt.
4 oz (113g)

Reorder No:
MPR-30604

En-Shield
SKIN PROTECTANT
ALOE SOFT • VITAMIN ENRICHED

| Drug Facts | |
|--|-----------------------------------|
| Active Ingredients (in each gram) Zinc oxide (1.8% w/w)..... | Purpose Skin Protectant |
| Uses <ul style="list-style-type: none"> ■ helps treat and prevent diaper rash ■ temporarily protects minor ■ cuts ■ scrapes ■ burns ■ dries the oozing and weeping of: Poison ivy ■ poison oak ■ poison sumac | |
| Warnings For external use only | |
| When using this product <ul style="list-style-type: none"> ■ 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 in a few days, consult a physician | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away | |
| Directions <ul style="list-style-type: none"> ■ change wet and soiled diapers promptly ■ cleanse the diaper area and allow to dry ■ apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged ■ for poison ivy, oak and sumac ■ apply ointment liberally as often as needed | |
| Other information ■ store at room temperature 15-30°C (59-86°F) ■ avoid excessive heat | |
| Inactive ingredients aloe vera leaf, alpha-tocopherol, ceteth-10, cetostearyl alcohol, cetyl alcohol, cholecalciferol, glycerin, lanolin, lavender, methyl paraben, mineral oil, paraffin, petrolatum, phenoxethanol, polyethylene glycol 6000, polysorbate 60, propylparaben sodium, steareth-20, trolamine, vitamin A, water, FD&C Yellow No.5, D&C Red No.21 | |

Reorder No: **MPR-30604**

Manufactured For
Shield Line LLC, Hackensack, NJ 07601
Made in India



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MEDPRIDE EN SHIELD ALOE SOFT VITAMIN ENRICHED

zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52410-3060 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 1.8 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY8 1Z83H0 X) | |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) | |
| CETETH-10 (UNII: LF9 X1PN3XJ) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128 M1S) | |
| CETYL ACETATE (UNII: 4Q438 14HXS) | |
| CHOLECALCIFEROL (UNII: 1C6 V77QF41) | |

| | |
|---|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| LANOLIN (UNII: 7EV65EAW6H) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PARAFFIN (UNII: I9O0E3H2ZE) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| PROPYL PARABEN SODIUM (UNII: 625NNB0G9N) | |
| STEARETH-20 (UNII: L0Q8IK9E08) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| VITAMIN A (UNII: 81G40H8B0T) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| D&C RED NO. 21 (UNII: 08744Z6JNY) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52410-3060-2 | 5 g in 1 PACKET; Type 0: Not a Combination Product | 05/27/2013 | |
| 2 | NDC:52410-3060-3 | 15 g in 1 PACKET; Type 0: Not a Combination Product | 05/27/2013 | |
| 3 | NDC:52410-3060-4 | 113 g in 1 TUBE; Type 0: Not a Combination Product | 05/27/2013 | |
| 4 | NDC:52410-3060-5 | 453 g in 1 JAR; Type 0: Not a Combination Product | 05/27/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 05/27/2013 | |

Labeler - Shield Line LLC (078518916)