

MEDPRIDE EN SHIELD- zinc oxide dimethicone 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)

Dimethicone 1.8%

Purpose

Skin Protectant

Skin Protectant

Uses

- helps treat and prevent diaper rash ■ 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

- conditions worsen ■ symptoms last more than 7 days or clear up and occur again in a few days, consult a physician ■ over large areas of the body ■ if you are allergic to any of these ingredients

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

- do not use if seal is punctured or not visible ■ 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

Package Label

Med PRIDE

En-Shield
WITH DIMETHICONE

Net Wt.
4 oz (113g)

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

Reorder No:
MPR-30654

Drug Facts

Active ingredients (in each gram)
Zinc Oxide (1.8% w/w) Skin Protectant
Dimethicone 1.8% Skin Protectant

Uses
■ helps treat and prevent diaper rash
■ 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
■ conditions worsen ■ symptoms last more than 7 days or clear up and occur again in a few days, consult a physician ■ cover large areas of the body ■ if you are allergic to any of these ingredients
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 often as needed

Other information
■ do not use if seal is punctured or not visible
■ 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, methylparaben, mineral oil, paraffin, petrolatum, phenoxyethanol, polyethylene glycol 6000, polysorbate 60, propylparaben sodium, steareth-20, trolamine, vitamin A, water

Reorder No: **MPR-30654**
Manufactured For
Shield Line LLC, Hackensack, NJ 07601
Made in India

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MEDPRIDE EN SHIELD

zinc oxide dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52410-3065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.8 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

CETETH-10 (UNII: LF9X1PN3XJ)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETYL ACETATE (UNII: 4Q43814HXS)
CHOLECALCIFEROL (UNII: 1C6V77QF41)
GLYCERIN (UNII: PDC6A3C0OX)
LANOLIN (UNII: 7EV65EAW6H)
LAVENDER OIL (UNII: ZBP1YXW0H8)
METHYL PARABEN (UNII: A218C7HI9T)
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: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52410-3065-4	113 g in 1 TUBE		

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)