

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

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: 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: 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		
2	NDC:52410-3060-3	15 g in 1 PACKET		
3	NDC:52410-3060-4	113 g in 1 TUBE		
4	NDC:52410-3060-5	453 g in 1 JAR		

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)