

ASTONEA EN SHIELD ALOE SOFT VITAMIN ENRICHED- zinc oxide cream
ASTONEA LABS PRIVATE LIMITED

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.

Astonea Skin Enshield

Active Ingredient

Zinc Oxide (3.8%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

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, Ceteth-20, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Ethylhexylglycerin, FD&C Yellow No. 5, Fragrance, Glycerin, Lanolin, Microcrystalline Wax, Mineral Oil, Paraffin, Phenoxyethanol, Ponceau 4R, Propylene Glycol, Sodium Benzoate, Vitamin A Palmitate, Water

Package Label

ASTONEA

En-Shield Zinc Oxide 3.8%

SKIN PROTECTANT

• ALOE SOFT

• ENRICHED WITH VITAMIN A, D & E

Net Wt.
3.5 oz. (99.2g)



ASTONEA En-Shield

SKIN PROTECTANT
ALOE SOFT • VITAMIN ENRICHED

Drug Facts

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

Inactive ingredients Aloe Vera Leaf,
Alpha-Tocopherol, Ceteth-20, Cetostearyl Alcohol,
Cetyl Alcohol, Cholecalciferol, Ethylhexylglycerin,
FD&C Yellow No. 5, Fragrance, Glycerin, Lanolin,
Light Mineral Oil, Microcrystalline Wax, Paraffin,
Phenoxyethanol, Propylene Glycol, Sodium
Benzoate, Vitamin A Palmitate, Water

Manufactured For:

Astonea Labs Private Limited
Village Haripur, Tehsil Raipurani,
Near Mouli Police Station, Panchkula, Haryana,
India - 134204 | Made in India

Made in India
HR/DRUGS 1105-OSP(H)

ASTONEA EN SHIELD ALOE SOFT VITAMIN ENRICHED

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	3.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CETETH-20 (UNII: I835H2IHHX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
PONCEAU 4R (UNII: Z525CBK9PG)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-306-64	99.2 g in 1 TUBE; Type 0: Not a Combination Product	02/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/07/2019	

Revised: 12/2022

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