ASTONEA-VITAMINS A AND D- petrolatum ointment 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 -Vitamins A and D

Drug Facts

Active ingredient

White Petrolatum USP (93.4%w/w)

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash
- Helps seal out wetness
- Temporarily protects minor
 - cuts
 - scrapes
 - burns
- Temporarily helps protect and relieve chapped and cracked skin or lips
- Helps prevent and protect from the drying effects of wind and cold weather
- Helps prevent and protect chafed skin or minor skin irritations associated with diaper rash
- With each diaper change, especially at bedtime when exposure to wetness may be prolonged

Warnings

For external use only

When using this product

Do not get into eyes

Stop Use and consult a doctor if

- condition worsens
- symptoms last more than 7 days
- symptoms clear up and reoccur in a few days

Do not use on

deep puncture wounds

- animal bites
- serious burns

Keep out of reach of children! If swallowed, get medical help or contact a Poison Control Center immediately

Directions for use with Diaper Rash

- change wet and soiled diaper promptly
- cleanse the diaper area and allow to dry
- apply as needed

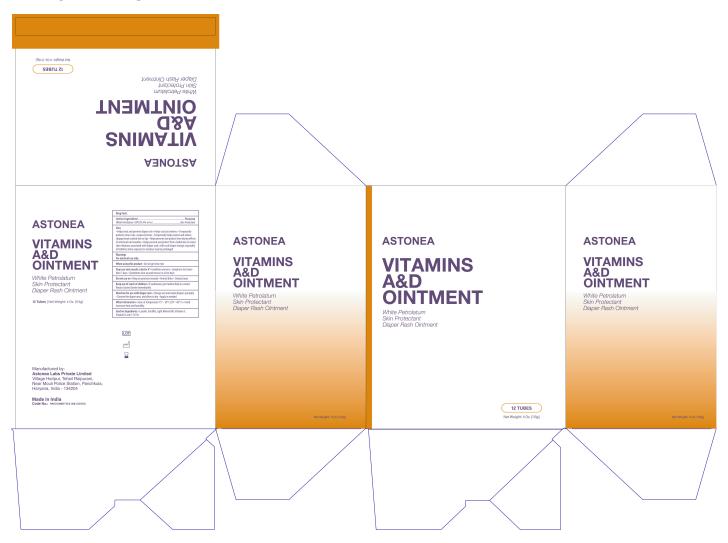
Other information

- store at 15°-30°C (59°-86°F)
- avoid excessive heat and humidity

Inactive Ingredients

Lanolin, Paraffin, Light Mineral Oil, Vitamin A, Vitamin D, CI 12740

PRINCIPAL DISPLAY PANEL



ASTONEA

VITAMINS A&D OINTMENT

White Petrolatum Skin Protectant Diaper Rash Ointment

> 4 Oz. Tube (113g)

Drug Facts

.......Purpose
.Skin Protectant

Uses

- Helps treat and prevent diaper rash Helps seal out wetness
- Temporarily protects minor cuts, scrapes and burns
- Temporarily helps protect and relieve chapped and cracked skin or lips - Helps prevent and protect from drying effects of wind and cold weather - Helps prevent and protect from chafed skin or minor skin irritations associated with diaper rash, with each diaper change, especially at bedtime when exposure to wetness may be prolonged

Warnings

For external use only.

When using this product • Do not get into eyes

Stop use and consult a doctor if • Condition worsens • Symptoms last more than 7 days • Symptoms clear up and reoccur in 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 Poison Control Center immediately

Direction for use with diaper rash • Change wet and soiled diapers promptly • Cleanse the diaper area, and allow to dry • Apply as needed

Other Information - Store at 15° - 30° C (59° - 86° F) - Avoid excessive heat and humidity

Inactive Ingredients • Lanolin, Paraffin, Light Mineral Oil, Vitamin A, Vitamin D and Cl 12740

ASTONEA

VITAMINS A&D OINTMENT

4 Oz. Tube (113g)

Manufactured by:

Astonea Labs Private Limited

Village Haripur, Tehsil Raipurani, Near Mouli Police Station, Panchkula, Haryana, India - 134204

Made in India

Code No.: HR/COSMETICS 308-COS(H)

ASTONEA-VITAMINS A AND D

petrolatum ointment

Product	LIMEAN	
Produci		mation

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.934 g in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
SOLVENT YELLOW 18 (UNII: L4SQI4K87S)			
LANOLIN (UNII: 7EV65EAW6H)			
PARAFFIN (UNII: 1900E3H2ZE)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
VITAMIN A (UNII: 81G40H8B0T)			
VITAMIN D (UNII: 9VU1KI44GP)			

	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:77338-105- 32	5 g in 1 PACKET; Type 0: Not a Combination Product	05/02/2022		
:	NDC:77338-105- 33	113 g in 1 TUBE; Type 0: Not a Combination Product	05/02/2022		
3	NDC:77338-105- 35	425 g in 1 JAR; Type 0: Not a Combination Product	05/02/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/02/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Establishment			
Name	Address	ID/FEI	Business Operations
ASTONEA LABS PRIVATE LIMITED		878533295	manufacture(77338-105)

Revised: 5/2022 ASTONEA LABS PRIVATE LIMITED