

**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.*

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**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)**

<b>Drug Facts</b>	
<b>Active Ingredient</b> .....	<b>Purpose</b>
White Petrolatum USP (93.4% w/w).....	Skin Protectant
<b>Uses</b>	
• 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	
<b>Warnings</b>	
For external use only.	
<b>When using this product</b> • Do not get into eyes	
<b>Stop use and consult a doctor if</b> • Condition worsens • Symptoms last more than 7 days • Symptoms clear up and reoccur in a few days	
<b>Do not use on</b> • Deep or puncture wounds • Animal bites • Serious burns	
<b>Keep out of reach of children</b> • If swallowed, get medical help or contact Poison Control Center immediately	
<b>Direction for use with diaper rash</b> • Change wet and soiled diapers promptly • Cleanse the diaper area, and allow to dry • Apply as needed	
<b>Other Information</b> • Store at 15° - 30° C (59° - 86° F) • Avoid excessive heat and humidity	
<b>Inactive Ingredients</b> • Lanolin, Paraffin, Light Mineral Oil, Vitamin A, Vitamin D and CI 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 Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-105
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SOLVENT YELLOW 18</b> (UNII: L4SQI4K87S)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>VITAMIN A</b> (UNII: 81G40H8B0T)	
<b>VITAMIN D</b> (UNII: 9VU1KI44GP)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77338-105-32	5 g in 1 PACKET; Type 0: Not a Combination Product	05/02/2022	
2	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

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

**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)

## Establishment

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

