

**ASTONEA VITAMIN A AND D- white 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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**VITAMIN A&D**

***Active Ingredient***

White Petroleum Jelly USP (76% 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 wet diapers may be prolonged

***Warnings***

**For external use only**

**When using this product**

■ do not get into eyes

**Stop use and ask a doctor if**

■ condition worsens ■ symptoms last more than 7 days or clear up and occur again in a few days

**Do not use on**

■ animal bites ■ deep or puncture wounds ■ serious burns

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away

## Directions

for Diaper Rash ■ change wet and soiled diapers promptly ■ cleanse the diaper area and allow to dry ■ apply as needed

## Other Information

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

## Inactive ingredients

Cholecalciferol, Lanolin, Light Mineral Oil, Microcrystalline Wax, Paraffin, Vitamin A Palmitate

## Package Label

<h1>Vitamins A&amp;D Ointment</h1> <p><b>ASTONEA</b> PETROLATUM USP 76%</p> <p>Net Wt.: 5g</p> <ul style="list-style-type: none"><li>• Diaper Rash Ointment</li><li>• Skin Protectant</li></ul> <p>TAMPER EVIDENT. DO NOT USE IF PACKET IS TORN OR CUT</p>						
<p>Manufactured for <b>Astonea Labs Private Limited</b> Village Haipur, Tehsil Raipur Raipurani, Near Mavi Polic Station, Panchkula, Haryana, India - 134204 Made in India HR/DRUGS 1105-OSP(H)</p>	<table border="1"><tr><td><b>Drug Facts</b></td></tr><tr><td><b>Active ingredient</b> Petrolatum USP (76% w/w) ..... Skin Protectant</td></tr><tr><td><b>Purpose</b></td></tr><tr><td><b>Uses:</b> ■ 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 wet diapers may be prolonged.</td></tr><tr><td><b>Important</b> ■ see box for complete Drug Facts, directions and additional information</td></tr></table>	<b>Drug Facts</b>	<b>Active ingredient</b> Petrolatum USP (76% w/w) ..... Skin Protectant	<b>Purpose</b>	<b>Uses:</b> ■ 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 wet diapers may be prolonged.	<b>Important</b> ■ see box for complete Drug Facts, directions and additional information
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white petrolatum ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-307
<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	76 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77338-307-02	5 g in 1 PACKET; Type 0: Not a Combination Product	05/23/2013	
2	NDC:77338-307-03	28.3 g in 1 TUBE; Type 0: Not a Combination Product	05/23/2013	
3	NDC:77338-307-04	113 g in 1 TUBE; Type 0: Not a Combination Product	05/23/2013	
4	NDC:77338-307-05	425 g in 1 JAR; Type 0: Not a Combination Product	05/23/2013	

### 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	05/23/2013	

**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(77338-307)

