

## **DIAPER RASH SKIN PROTECTANT- lanolin and petrolatum ointment**

### **Universal Distribution Centre 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.*

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### **Diaper Rash Ointment**

Distributed by Bayer HealthCare LLC, Whippany, NJ, USA, 07981

<b>Active ingredients</b>	<b>Purpose</b>
Lanolin 15.5%	Diaper rash ointment
Petrolatum 53.4%	Skin Protectant

### **Uses**

- helps treat and prevent diaper rash
- temporarily protects minor:
  - cuts
  - scrapes
  - burns
- temporarily protects and helps relieve chapped, chafed or cracked skin and lips
- protect chafed skin due to diaper rash and helps seal out wetness

### **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 within 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 a Poison Control Center right away.

### **Directions**

- **for skin protectant use** apply as needed
- **for diaper rash use:**

- change wet and soiled diapers promptly
- cleanse the diaper area, and allow to dry
- apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

### **Other information**

store between 20°C to 25 °C (68° to 77°F)

### **Inactive Ingredients**

cod liver oil ( contains vitamin A & vitamin D), fragrance, light mineral oil, microcrystalline wax, paraffin

**PRINCIPAL DISPLAY PANEL - 35.4g Carton**

82700 1.25 OZ DIAPER RASH OINTMENT-24

**New**

# DIAPER RASH OINTMENT

**SKIN PROTECTANT** Lanolin 15.5%  
Petrolatum 53.4%

- Helps prevent & treat diaper rash
- Forms a protective barrier to help seal out wetness

**A+D® Original**  
Ointment active ingredients

**MAXIMUM STRENGTH**

**WETTEST A&D**

Net Wt. 1.25 oz (35.4g)

+

**DIAPER RASH & SKIN PROTECTANT OINTMENT WITH VITAMIN A & D**

- Helps Seal Out Wetness
- Helps Treat & Prevent Diaper Rash
- Hypoallergenic
- Gentle On Baby's Skin



**New**

# DIAPER RASH OINTMENT

**SKIN PROTECTANT** Lanolin 15.5%  
Petrolatum 53.4%

Net Wt. 1.25 oz (35.4g)

**DIAPER RASH OINTMENT**

**SKIN PROTECTANT**

Helps prevent & treat diaper rash  
Forms a protective barrier to help seal out wetness  
Net Wt. 1.25 oz (35.4g)

**DISTRIBUTED BY**  
Universal Distribution Center  
96 Distribution Boulevard, Heller Industrial  
Park Edison, New Jersey 08817  
www.universalbrandusa.com



Batch No: 2061001

Mfg. Date: JAN. 2021

Exp. Date: DEC. 2023

Code : MH/DRUGS/KD-251

Item#82700



7 6979 82700 1

Made in India

**DRUG FACTS**

<p><b>Purpose</b> Diaper Rash Ointment Skin Protectant</p> <p><b>Active ingredient</b> Lanolin 15.5% Petrolatum 53.4%</p> <p><b>USES</b> • Helps treat and prevent diaper rash • temporarily protects minor: • scrapes • burns • protect chafed skin due to diaper rash and helps seal out wetness • temporarily protects and helps relieve chapped, chafed or cracked skin and lips</p> <p><b>WARNING: EXTERNAL USE ONLY</b></p> <p><b>When using this product:</b> • DO NOT get into eyes</p> <p><b>STOP USE and ask a doctor if</b> • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days</p> <p><b>Inactive ingredients</b> odd lot of (contains vitamin A and vitamin D), fragrance, light mineral oil, microcrystalline wax, glycerin</p> <p><b>Other information</b> • store at 20° to 25° C (68° - 77° F) • DO NOT use if tube seal under cap is broken, missing or if tube tip is out prior to opening</p> <p><b>DIRECTIONS</b> • for skin protectant use apply as needed • for diaper rash use: • cleanse the diaper area, and allow to dry • apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged</p> <p><b>DO NOT USE if you have</b> • deep or puncture wounds • animal bites • serious burns</p> <p><b>KEEP OUT OF REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</p>	<p><b>When using this product:</b> • DO NOT get into eyes</p> <p><b>STOP USE and ask a doctor if</b> • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days</p> <p><b>Inactive ingredients</b> odd lot of (contains vitamin A and vitamin D), fragrance, light mineral oil, microcrystalline wax, glycerin</p> <p><b>Other information</b> • store at 20° to 25° C (68° - 77° F) • DO NOT use if tube seal under cap is broken, missing or if tube tip is out prior to opening</p> <p><b>DIRECTIONS</b> • for skin protectant use apply as needed • for diaper rash use: • cleanse the diaper area, and allow to dry • apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged</p> <p><b>DO NOT USE if you have</b> • deep or puncture wounds • animal bites • serious burns</p> <p><b>KEEP OUT OF REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</p>
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This product is NOT manufactured or distributed by H&M Consumer Care, Inc., the distributor of A+D® Original Diapers.

**New**

# DIAPER RASH OINTMENT

**SKIN PROTECTANT**

Helps prevent & treat diaper rash  
Forms a protective barrier to help seal out wetness

**A+D® Original**  
Ointment active ingredients

CYAN MAGENTA YELLOW BLACK

Size : 60 X 30 X 40 X 100 X 153 MM

# DIAPER RASH SKIN PROTECTANT

lanolin and petrolatum ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52000-073
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LANOLIN</b> (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	136.4 mg in 1 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	469.9 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>COD LIVER OIL</b> (UNII: BBL281NWFQ)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	

## Product Characteristics

<b>Color</b>	orange (Unctuous amber mass)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-073-02	1 in 1 CARTON	01/25/2021	
1	NDC:52000-073-01	35.4 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/25/2021	

**Labeler** - Universal Distribution Centre LLC (019180459)

**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)

## Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceutical Pvt. Ltd		916837425	manufacture(52000-073)

Revised: 2/2022

Universal Distribution Centre LLC