

## **VITAMIN A D - petrolatum ointment**

### **Dynarex Corporation**

*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          | Purpose         |
|----------------------------|-----------------|
| White Petrolatum USP (76%) | Skin Protectant |

### **Uses: Vitamin\_A\_D**

- Helps treat and prevent diaper rash
- Helps seal out wetness
  
- Temporarily protects minor \* cuts \* scrapes \* burns
- Temporarily helps protect and help relieve chapped and cracked skin and 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**

#### **Do Not Get In Eyes**

#### **Stop use and ask a doctor if:**

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

#### **Do not use on:**

Do not use on:

- Deep or puncture wounds
- animal bites
- serious burns

#### **Keep out of reach of children**

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 room temperature 15 deg C to 30 deg C 59 deg F to 86 deg F

- Avoid excessive heat

## Inactive Ingredients

Inactive Ingredients: Lanolin, Lavender Oil, Light Liquid Paraffin, Vitamin A, Vitamin D


## Indications and Usage

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A skin protectant for the treatment of diaper rash, minor cuts, scrapes, burns and to help relieve chapped and cracked skin and lips.

## Principal Display Panel

Vitamin\_A\_D

|  |                                   |   |   |   |
|--|-----------------------------------|---|---|---|
| <b>Drug Facts</b>  |                                   | <b>Drug Facts (continued)</b>   |   | <b>Manufactured for:</b><br>Dynarex Corporation<br>Orangeburg, NY 10962<br>www.dynarex.com<br><b>NDC #67777-214-01</b><br>Made in India<br><br>6 16784 11551 1 |
| <b>Active ingredient</b><br>White Petrolatum USP (76% w/w)   | <b>Purpose</b><br>Skin Protectant | <b>Do not use on</b> • deep or puncture wounds • animal bites<br>• serious burns  | <b>Keep out of reach of children</b><br>• If swallowed, get medical help or contact a Poison Control Center right away. |   |
| <b>Uses:</b><br>• Helps treat & prevent diaper rash<br>• Helps seal out wetness<br>• Temporarily protects minor • cuts • scrapes • burns<br>• Temporarily helps protect and help relieve chapped and cracked skin or lips.<br>• Helps prevent and protect from the drying effects of wind and cold weather.<br>• Helps prevent and protect chafed skin or minor skin irritations associated with diaper rash.<br>• With each diaper change, especially at bedtime when exposure to wet diapers may be prolonged. |                                   | <b>Directions For Diaper Rash:</b><br>• Change wet and soiled diapers promptly<br>• Cleanse the diaper area and allow to dry<br>• Apply as needed |   |   |
| <b>Warnings • For External Use Only</b><br>When using this product • Do not get into eyes<br>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   |                                   | <b>Other Information</b><br>• Store at room temperature 15° - 30° C (59° to 86°F)<br>• Avoid excessive heat                                       |   |   |
|  |                                   | <b>Inactive Ingredients:</b><br>• Lanolin, Lavender Oil, Light Liquid Paraffin, Vitamin A, Vitamin D  |   |   |

## VITAMIN A D

petrolatum ointment

### Product Information

|                                |                      |                           |               |
|--------------------------------|----------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG LABEL | <b>Item Code (Source)</b> | NDC:67777-214 |
| <b>Route of Administration</b> | TOPICAL              | <b>DEA Schedule</b>       |               |

### Active Ingredient/Active Moiety

| Ingredient Name         | Basis of Strength | Strength     |
|-------------------------|-------------------|--------------|
| PETROLATUM (PETROLATUM) | PETROLATUM        | .76 g in 1 g |

**Inactive Ingredients**

| Ingredient Name     | Strength |
|---------------------|----------|
| VITAMIN A PALMITATE |          |
| CHOLECALCIFEROL     |          |
| LANOLIN             |          |
| LIGHT MINERAL OIL   |          |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:67777-214-01 | 12 in 1 CASE        |                      |                    |
| 1 |                  | 6 in 1 BOX          |                      |                    |
| 1 |                  | 113.4 g in 1 TUBE   |                      |                    |
| 2 | NDC:67777-214-02 | 12 in 1 CASE        |                      |                    |
| 2 |                  | 425.25 g in 1 JAR   |                      |                    |
| 3 | NDC:67777-214-03 | 72 in 1 CASE        |                      |                    |
| 3 |                  | 28.35 g in 1 TUBE   |                      |                    |
| 4 | NDC:67777-214-04 | 72 in 1 CASE        |                      |                    |
| 4 |                  | 1 in 1 BOX          |                      |                    |
| 4 |                  | 28.35 g in 1 TUBE   |                      |                    |
| 5 | NDC:67777-214-05 | 72 in 1 CASE        |                      |                    |
| 5 |                  | 56.7 g in 1 TUBE    |                      |                    |
| 6 | NDC:67777-214-06 | 72 in 1 CASE        |                      |                    |
| 6 |                  | 1 in 1 BOX          |                      |                    |
| 6 |                  | 56.7 g in 1 TUBE    |                      |                    |
| 7 | NDC:67777-214-07 | 72 in 1 CASE        |                      |                    |
| 7 |                  | 1 in 1 BOX          |                      |                    |
| 7 |                  | 113.4 g in 1 TUBE   |                      |                    |
| 8 | NDC:67777-214-08 | 6 in 1 CASE         |                      |                    |
| 8 |                  | 144 in 1 BOX        |                      |                    |
| 8 |                  | 5 g in 1 PACKET     |                      |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347                                  | 03/24/2010           |                    |

**Labeler** - Dynarex Corporation (008124539)**Registrant** - Dynarex Corporation (008124539)