

A AND D PLUS E - petrolatum ointment
H&H Laboratories, Inc.

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.

DRUG FACTS

Active Ingredient (in each gram): White Petrolatum 93.5%

Purpose-Skin Protectant

Uses-Temporarily protects minor cuts, scrapes, and sunburn. Helps treat and prevent diaper rash. Protects chafed skin or minor skin irritation associated with diaper rash and helps seal out wetness. Temporarily protects and helps chapped or cracked skin and lips. Helps protect lips from drying effects of wind and cold weather.

Directions: Apply liberally as needed Change wet and soiled diapers promptly. Cleanse the diaper area and allow to dry. Use with each diaper change, especially at bedtime when exposure to wet diapers may be prolonged.

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

For external use only. Do not use in eyes, on deep puncture wounds, animal bites, or serious burns or for more than 1 week unless directed by a doctor.

Stop use and ask a doctor if: A rash or allergic reaction develops. Condition worsens, persists, or recurs.

Inactive Ingredients: Corn Oil, Light Mineral Oil, Vitamin A Palmitate, Vitamin D, Vitamin E

MM1

NDC 52471-100-04

A&D+E Ointment

Contains Vitamins A, D & E
for skin protection and to
aid in healing



sterex
MEDICAL

NET WT. 4 OZ. AV. (113.4g) For External Use Only



DRUG FACTS

| <i>Active Ingredient</i> | <i>Purpose</i> |
|--------------------------|-----------------|
| White petrolatum USP | Skin Protectant |

Directions:

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

Uses:

Helps treat and prevent diaper rash
Protects chafed skin due to diaper rash and helps protect from wetness
Helps prevent and temporarily protects chafed, chapped, cracked, or wind burned skin & lips
Temporary protection of minor cuts, scrapes, burns, sunburn, chafed or chapped skin

Warnings:

- For external use only**
- Avoid contact with eyes
- Not to be applied over deep puncture wounds, infections or lacerations
- Stop use and ask doctor if condition worsens or does not improve within 7 days
- If swallowed, get medical help or contact a Poison Control Center right away
- Keep out of reach of children**

Other Information:

Store at room temperature 59° to 86° F
Lot No. see box or crimp of tube

Inactive Ingredient

Petrolatum, Vitamin A Palmitate, Vitamin D, and Vitamin E

www.sterexmedical.com

Manufactured by:
H&H Labs , Brooklyn, NY 11231



DRUG FACTS
Active Ingredient: White petrolatum.
Purpose: Skin protectant.

Uses:

- Helps treat and prevent diaper rash
- Protects chafed skin or minor skin irritation associated with diaper rash and helps seal out wetness.
- Helps prevent and temporarily protects chafed, chapped, cracked or wind burned skin and lips.
- Provides temporary protection of minor cuts, scrapes, burns and sunburns.

Warnings:

- For external use only.
- Do not use over deep or puncture cuts, wounds, infections or lacerations.
- When using this product avoid contact with eyes.
- Stop use and ask a doctor if condition worsens or does not improve within 7 days.

Directions:

- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
- Apply liberally as often as necessary.
- Change wet and soiled diapers promptly.
- Cleanse the diaper area, and allow to dry.
- Use with each diaper change, especially at bedtime when exposure to wet diapers may be prolonged.

Other Information:

- Store at room temperature (15 to 30 C / 59 to 86 F)
- Lot No. and Exp. date see the bottom of the container.

Inactive Ingredients:
 Petrolatum, vitamin A palmitate and vitamin D, vitamin E.

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 BROOKLYN, N.Y. 11231
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MADE IN U.S.A.

NDC 52471- 100-13

**VITAMIN A AND D + E
 OINTMENT**

Contains Vitamins A and D
 in a Petrolatum Base
 FOR EXTERNAL USE ONLY
 NET WT. 13 OZ. (368 gms)

A AND D PLUS E
 petrolatum ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52471-100 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------|-------------------|-----------------|
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 937.5 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------------------------|----------|
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| ERGO CALCIFEROL (UNII: VS041H42XC) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:52471-100-04 | 113 g in 1 TUBE | | |
| 2 | NDC:52471-100-13 | 168 g in 1 JAR | | |
| 3 | NDC:52471-100-16 | 454 g in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part347 | 05/14/2012 | |

Labeler - H&H Laboratories, Inc. (151357175)

