

**COTTONTAILS DIAPER RASH- lanolin, petrolatum paste
AMERICAN SALES COMPANY**

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 INGREDIENTS

LANOLIN 15.5%

PETROLATUM 53.4%

PURPOSE

SKIN PROTECTANT

USES

HELPS TREAT AND PREVENT DIAPER RASH. TEMPORARILY PROTECTS MINOR CUTS, SCRAPES AND BURNS. TEMPORARILY PROTECTS AND RELIEVES CHAPPED, CHAFED OR CRACKED SKIN. HELPS PROTECT FROM THE DRYING EFFECTS OF WIND AND COLD WEATHER

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER THOROUGHLY

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

CONDITION WORSENS. SYMPTOMS LAST MORE THAN 7 DAYS. IF SYMPTOMS 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

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY

DIRECTIONS

FOR SKIN PROTECTANT USE. APPLY AS NEEDED.

FOR DIAPER RASH USE. CHANGE WET AND SOILED DIAPERS PROMPTLY. CLEAN THE DIAPER AREA AND ALLOW TO DRY. APPLY OINTMENT AS OFTEN AS REQUIRED WITH EACH DIAPER CHANGE, ESPECIALLY AT BEDTIME OR ANYTIME WHEN EXPOSURE TO WET DIAPERS MAY BE PROLONGED

OTHER INFORMATION

STORE BETWEEN 20°-25°C (68°-77°F)

INACTIVE INGREDIENTS

MICROCRYSTALLINE WAX, MINERAL OIL, PARAFFIN, FRAGRANCE (PARFUM), COD LIVER OIL (VITAMINS A & D)

QUESTIONS OR COMMENTS?

1-866-695-3030

LABEL COPY

Compare to the active ingredients in A+D® Original Ointment*

diaper rash ointment



baby care

paraben free

helps heal dry, chafed skin

helps soothe and prevent diaper rash

vitamins A & D

NET WT 4 OZ (113g)

Drug Facts

Active Ingredients

Purpose

Lanolin 15.5%..... Skin protectant
Petrolatum 53.4%..... Skin protectant

Uses ■ Helps treat and prevent diaper rash. ■ Temporarily protects minor cuts, scrapes and burns. ■ Temporarily protects and relieves chapped, chafed or cracked skin. ■ Helps protect from the drying effects of wind and cold weather.

Warnings

For external use only.

When using this product

■ Avoid contact with eyes. If contact occurs, rinse with water thoroughly.

Stop using this product and ask a doctor if

■ Conditions worsen.
■ Symptoms last more than 7 days.
■ If symptoms 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. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

■ For skin protectant use.
■ Apply as needed. ■ For diaper rash use.
■ Change wet and soiled diapers promptly.
■ Clean the diaper area and allow to dry.
■ Apply ointment as often as required with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other Information

■ Store between 20°-25°C (68°-77°F)

Inactive Ingredients: Microcrystalline Wax, Mineral Oil, Paraffin, Fragrance (Paraffin), Cod Liver Oil (Vitamins A & D).

Questions or Comments?

1-866-695-3030

DISTRIBUTED BY FOODHOLD U.S.A., LLC
LANDOVER, MD 20785

1-877-846-9949

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MADE IN CANADA

Quality guaranteed or your money back.

*This product is not manufactured or distributed by Merck/MSD Consumer Care, Inc., distributor of A+D® Original Ointment.

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COTTONTAILS DIAPER RASH

lanolin, petrolatum paste

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41520-341 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H) | LANOLIN | 155 mg in 1 g |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 534 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PARAFFIN (UNII: I9O0E3H2ZE) | |
| COD LIVER OIL (UNII: BBL281NWFG) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:41520-341-04 | 113 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part347 | 12/16/2013 | |

Labeler - AMERICAN SALES COMPANY (809183973)**Registrant** - APOLLO HEALTH AND BEAUTY CARE (201901209)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|----------------|---------------|----------------------------|
| APOLLO HEALTH AND BEAUTY CARE | | 201901209 | manufacture(41520-341) |

Revised: 12/2013

AMERICAN SALES COMPANY