

VITACILINA BEBE DIAPER RASH- allantoin, zinc oxide ointment
Compania Internacional de Comercio, S.A.P.I de C.V.

VITACILINA Bebe Diaper Rash Ointment

Drug Facts

Active ingredients

Allantoin 1% Zinc Oxide 25%

Purpose

Skin Protectant

Uses

- Treats and prevents diaper rash
- Protects minor skin irritation associated with diaper rash
- Helps seal out wetness

Warnings

- For external use only
- Avoid contact with the eyes
- If condition worsens or does not improve within 7 days, consult a doctor

Keep out of the reach of children

Directions

Change wet and soiled diapers promptly, cleanse the diaper area and allow to dry. Apply ointment as often as necessary with each diaper change, especially at bedtime or anytime when exposure to wet diapers maybe prolonged.

Inactive Ingredients

Petrolatum, corn starch, fragrance, lanolin, methylparaben, mineral oil, propylparaben, vitamin A (palmitate), vitamin D (calciferol), vitamin E (tocopherol).

Package Labeling:

SKIN PROTECTANT ■ ENRICHED WITH VITAMINS AND WETTING OILS







 VITAMINS A D & E

NDC 54312-525-16
 Diaper Rash Ointment
Bebé

VITACILINA®

(50 g)
 NET WT 1.76 OZ

LOT: EXP. DATE

Drug Facts

| | |
|---------------------------|----------------------|
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| Allantoin 1%..... |Skin Protectant |
| Zinc Oxide 25%..... |Skin Protectant |

Uses • Treats and prevents diaper rash • Protects minor skin irritation associated with diaper rash • Helps seal out wetness

DISTRIBUTED BY Taisho Pharmaceutical California Inc. 3528 Torrance Blvd, Suite #320 Torrance, CA 90503 U.S.A. MADE IN MEXICO

NET WT 1.76 OZ (50 g)

VITACILINA®

Bebé

Diaper Rash Ointment
NDC 54312-525-16

VITAMINS A D & E







 VITAMINS A D & E
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SKIN PROTECTANT ■ ENRICHED WITH VITAMINS AND WETTING OILS

Drug facts (continued)

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30128-V4

SKIN PROTECTANT ■ ENRICHED WITH VITAMINS AND WETTING OILS

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30538-V4

LOT. EXP. DATE

VITACILINA BEBE DIAPER RASH

allantoin, zinc oxide ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:54312-525 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | ALLANTOIN | 10 mg in 1 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 250 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| PETROLATUM (UNII: 4T6H12BN9U) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| LANOLIN (UNII: 7EV65EAW6H) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| VITAMIN A (UNII: 81G40H8B0T) | |
| VITAMIN D (UNII: 9VU1KI44GP) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:54312-525-16 | 1 in 1 PACKAGE | 09/30/2013 | |
| 1 | | 50 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 Drug | M016 | 09/30/2013 | |

Labeler - Compania Internacional de Comercio, S.A.P.I de C.V. (822165213)