# ANGEL OF MINE DIAPER RASH- zinc oxide ointment Wenzhou Senos Cosmetics Technology Co., Ltd.

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

**Drug Facts** 

#### **Active ingredient**

Zinc Oxide 16%

#### **Purposes**

Skin Protectant

#### Uses

- Helps treat and prevent diaper rash
- Prevents chafed skin due to diaper rash
- Helps seal out wetness

#### **Warnings**

For external use only.

#### When using this product

- avoid contact wih eyes
- this product contains chemicals, including lead, known to the State of California to case birth defects or othr reproductive harm

#### Stop use and ask a doctor if

- Condition worsens
- or does not improve within 7 days

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

#### **Directions**

- Change wet or soiled diapers promptly
- Clean the diaper area and allow to dry
- Apply iubtnebt liberally as often as necessary, with each diaper change, especially at bedtime or any time prolonged exposure to wet diapers may be prolonged.

#### **Inactive ingredients**

boric acid, castor ol, fragrance, microcrystalline wax, mineral oil, paraffin, petrolatum

#### PRINCIPAL DISPLAY PANEL

#### Angel of mine™

diaper rash Ointment

- Soothes the rash
- Helps heal
- Wipes of easily

Net Wt. 2 oz. (56g)



#### ANGEL OF MINE DIAPER RASH

zinc oxide ointment

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58638-002

| <b>-</b> | •  |          |       |         |
|----------|----|----------|-------|---------|
| Panta    | Λŧ | $\Delta$ | minic | tration |
|          |    |          |       |         |

TOPICAL

|  | Active | Ingre | dient/ | Active | Moiety |
|--|--------|-------|--------|--------|--------|
|--|--------|-------|--------|--------|--------|

| reave ingredient/reave wrotery                               |                   |               |
|--|-------------------|---------------|
| Ingredient Name  | Basis of Strength | Strength      |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 160 mg in 1 g |

| Inactive Ingredients                     |          |  |  |  |
|--|----------|--|--|--|
| Ingredient Name                          | Strength |  |  |  |
| BORIC ACID (UNII: R57ZHV85D4)            |          |  |  |  |
| CASTOR OIL (UNII: D5340 Y2I9 G)          |          |  |  |  |
| MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY) |          |  |  |  |
| MINERAL OIL (UNII: T5L8T28FGP)           |          |  |  |  |
| PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E )     |          |  |  |  |
| PETRO LATUM (UNII: 4T6H12BN9U)           |          |  |  |  |

### Packaging

| # Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|--------------------|---|----------------------|--------------------|
| 1 NDC:58638-002-01 | 56 g in 1 TUBE; Type 0: Not a Combination Product | 05/22/2017           |                    |

### **Marketing Information**

| OTC monograph final part347 05/22/2017 | Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--|---------------------|--|----------------------|--------------------|
|  | OTC monograph final | part347                                  | 05/22/2017           |                    |

# Labeler - Wenzhou Senos Cosmetics Technology Co., Ltd. (420430722)

## Registrant - Wenzhou Senos Cosmetics Technology Co., Ltd. (420430722)

| Establishment                                |         |           |                            |
|--|---------|-----------|----------------------------|
| Name   | Address | ID/FEI    | <b>Business Operations</b> |
| Wenzhou Senos Cosmetics Technology Co., Ltd. |         | 420430722 | manufacture(58638-002)     |

Revised: 5/2017 Wenzhou Senos Cosmetics Technology Co., Ltd.