# DR. SMITHS RASH AND SKIN- zinc oxide ointment Mission Pharmacal 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.

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## Dr. Smith's ® Rash+Skin

## **Drug Facts**

| Active Ingredient | Purpose         |
|-------------------|-----------------|
| Petrolatum 57%    | Skin Protectant |
| Lanolin 16%       | Skin Protectant |

### Uses

temporarily protest minor:

- cuts
- scrapes
- burns

Temporarily protects and helps relieve chapped, chafed, or cracked skin.

Helps protect from the dying effects of wind and cold weather.

Helps treat and prevent rash caused by adult incontinence.

## **Warnings**

For external use only.

When using this product, avoid contact with eyes.

**See a doctor** if condition lasts more than 7 days.

### Do not use on

- deep or puncture wounds
- animal bites
- serious burns

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

### Directions

Apply as needed to affected area.

## **Other Information**

Store at  $20^{\circ} - 25^{\circ}\text{C} (68^{\circ} - 77^{\circ} \text{ F})$ 

beeswax, mineral oil, olive oil, paraffin wax, purified water, thymol iodide, zinc oxide.

To report a serious adverse event or obtain product information, call (210) 696-8400

MISSION PHARMACAL COMPANY San Antonio, TX 78230-1355

51023 Rev 011120

Dr Smith's Rash+Skin Ointment Carton

NDC: 0178-0370-03



Para el Alivio y la Prevención

de las erupciones e irritaciones de la piel

NDC 0178-0370-03





For the of skin rash

Helps treat and prevent rash caused by adult incontinence



NET WT 3 0Z (85g)

A protective barrier is created by the application of Dr. Smith's that effectively seals out moisture and helps promote healing of skin irritation.

- · Goes on like a cream-protects like an ointment®
- · Easy to apply
- · Easy to wash off

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Goes on like a cream.



### Información del Medicamento

Ingrediente activo Propósito Petrolato 57%. Protector de la piel Lanolina 16%. Protectora de la piel

Protege temporalmente de leves m cortes m raspaduras m quemaduras

protage temporalmente y syuda a aliviar la pied irritada, exceriada o agrietada ayuda a protager de los efectos desecantes del viento y el frío seca la supuración y secreción causada por

## Advertencias Para uso externo solar

Al usar este producto, evite el contacto con los cios.

Consulte al médico si la condición dura más de 7 días

No debe usarse en mheridas profundas o punzantes mordeduras de animales quemaduras serias

Mantenga este y todo otro medicamento fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o contacte un Centro de Control de Envenenamientos

## Instrucciones - Aplicar según sea necesario en la zona

## Otra información Almacenar a 20° - 25° C (68° - 77°F)

Ingredientes inactivos

# Cera de abejas, aceite mineral, aceite de oliva, cera de parafina, agua purificada, yoduro de timol, óxido de zinc.

Para reportar un evento adverso serio o para obtener información sobre el producto, sirvase llamar al (210) 696-3400.

## doctorsmiths.com

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Mission



NDC 0178-0370-03

Relief and Prevention

of skin rash and chafing

Helps treat and prevent rash caused

adult incontinence

by

Great for all ages.

NET WT 3 0Z (85g)

MP0165

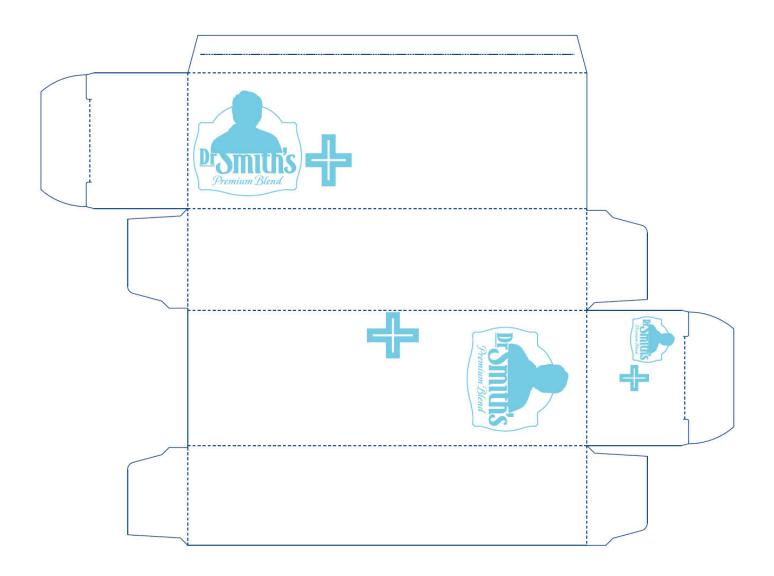


protects like an ointment\*



Relief and Prevention and chafing

Great for all ages.



## DR. SMITHS RASH AND SKIN

zinc oxide ointment

| Product | Information |
|---------|-------------|

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0178-0370

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 10 g in 100 g |

| Inactiva | Ingredients |
|----------|-------------|
| HIACHVE  | THEFT       |

| Inactive Ingredients          |                  |  |  |
|-------------------------------|------------------|--|--|
| Ingredient Name               | Strength         |  |  |
| PETROLATUM (UNII: 4T6H12BN9U) | 57.18 g in 100 g |  |  |
| LANOLIN (UNII: 7EV65EAW6H)    | 16.05 g in 100 g |  |  |
| ZINC OXIDE (UNII: SOI2LOH54Z) | 10 g in 100 g    |  |  |

| MINERAL O IL (UNII: T5L8T28FGP)     | 6.60 g in 100 g |
|-------------------------------------|-----------------|
| WATER (UNII: 059QF0KO0R)            | 4.60 g in 100 g |
| WHITE WAX (UNII: 7G1J5DA97F)        | 2.07 g in 100 g |
| OLIVE OIL (UNII: 6UYK2W1W1E)        | 2 g in 100 g    |
| THYMOL IODIDE (UNII: A51HJM3XSU)    | 1 g in 100 g    |
| PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E) | .5 g in 100 g   |

|   | Packaging          |                     |                      |                    |
|---|--------------------|---------------------|----------------------|--------------------|
| Ш | # Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|   | 1 NDC:0178-0370-03 | 1 in 1 CARTON       |                      |                    |
|   | 1                  | 100 g in 1 TUBE     |                      |                    |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part348                                  | 05/01/2013           |                    |
|                         |  |                      |                    |

# Labeler - Mission Pharmacal Company (008117095)

# Registrant - Mission Pharmacal Company (927726893)

| Establishment             |         |           |                        |  |
|---------------------------|---------|-----------|------------------------|--|
| Name                      | Address | ID/FEI    | Business Operations    |  |
| Mission Pharmacal Company |         | 927726893 | MANUFACTURE(0178-0370) |  |

Revised: 4/2013 Mission Pharmacal Company