DR SMITHS DIAPER- zinc oxide ointment
MainPointe Pharmaceuticals, LLC

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.

Dr. Smith's Diaper Rash Ointment

Active Ingredient

Zinc Oxide 10%

Purpose

Skin Protectant

Uses

helps treat and prevent diaper rash
protects chafed skin due to diaper rash and helps seal out wetness

Warnings

For external use only

When using this product, avoid contact with the eyes.

See a doctor if condition lasts more than 7 days.

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

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

Storage and Handling

Store between 15 0 and 30 0 C (59 0 and 86 0 F)

Inactive Ingredients

Beeswax, lanolin, mineral oil, olive oil, paraffin wax, petrolatum, purified water, thymol iodide

To report a serious adverse event of obtain product information, call (502)709-7544.

A Calming Cure for Every Bottom

Pediatrician Dr. Forrest Smith began his practice in 1952 with one goal in mind: to help his little patients. When it came to curing diaper rash, he was unsatisfied with the existing treatments. Joining forces with two pharmacist colleagues, he created his own ointment that would quickly relieve even the most uncomfortably irritated skin. Today, you can count on Moisture Shield Technology, found in every one of Dr. Smith's® ointments and sprays, to relieve and soothe sensitive skin. Dr. Smith's clinical formula, coupled with a love of giving back, went a long way towards making lives better—which is still what Dr. Smith's is all about.

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 10%	Skin Protectant

Uses
- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps seal out wetness

Warnings

For external use only

When using this product
- avoid contact with eyes

Stop use and ask a doctor if
- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

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

Directions
- change wet and soiled diapers promptly
- cleanse the diaper area
- allow to dry
- apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diaper may be prolonged

Other Information
- store at 20°-25°C (68°-77°F)

Inactive Ingredients
Beeswax, lanolin, mineral oil, olive oil, paraffin wax, petrolatum, purified water, thymol iodide

To report a serious adverse event or obtain product information, call 502-709-7544.

71269-006-03

QUICK RELIEF
DIAPER OINTMENT | 10% ZINC OXIDE

+ Treats & Prevents Diaper Rash
+ Gently Protects Delicate Skin

Infants & Toddlers

Para Tratar y Prevenir la Rozadura de Pañal RÁPIDAMENTE

NET WT 3 OZ (85g) TUBE

Dr. Smith's®
A Calming Cure for Every Bottom

PEDIATRICIAN APPROVED

Dr. Smith's

Datos del fármaco

Principio activo	Propósito
Óxido de zinc 10 %	Protector de la piel

Usos
- ayuda a tratar y a prevenir la dermatitis del pañal
- protege la piel irritada debido a la dermatitis del pañal y ayuda a bloquear la humedad

Advertencias

Solo para uso externo

Al usar este producto
- evitar contacto visual

Interrumpa el uso y consulte a un médico si
- la afección empeora
- los síntomas duran más de 7 días o desaparecen, y pueden volver a manifestarse al cabo de unos pocos días

Mantenga el producto fuera del alcance de los niños. Si se ingiere, obtenga ayuda médica o comuníquese con un Centro de Toxicología de inmediato.

Indicaciones
- cambie los pañales mojados y sucios con prontitud
- limpie el área del pañal
- déjela secar
- aplique la pomada con libertad, según sea necesario, con cada cambio de pañal, especialmente a la hora de dormir o en cualquier momento cuando la exposición a un pañal mojado sea prolongada

Otra información
- almacene el producto a una temperatura entre 20° y 25° C (68° y 77° F)

Principios inactivos
Cera de abeja, lanolina, aceite mineral, aceite de oliva, cera de parafina, petrolato, agua purificada, yoduro de timol

Para informar un evento adverso grave u obtener información sobre el producto, llame al 502-709-7544.

Lot number on end flap of carton.
51003R1218

DrSmiths.com

Distributed by:
MainPointe Pharmaceuticals, LLC
Louisville, KY 40202

MainPointe Pharmaceuticals, LLC

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NET WT 3 OZ (85g) TUBE

MP0388

DR SMITHS DIAPER

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71269-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
YELLOW WAX (UNII: 2ZA36H0S2V)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
THYMOL IODIDE (UNII: A51HJM3XSU)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71269-006-03	85 g in 1 TUBE; Type 0: Not a Combination Product	01/19/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/19/2018	

Labeler - MainPointe Pharmaceuticals, LLC (080544378)

Registrant - Mission Pharmacal (927726893)

Revised: 2/2020 MainPointe Pharmaceuticals, LLC