

DR. SHEFFIELD DIAPER RASH- zinc oxide ointment
Sheffield 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.

Drug Facts

Active ingredient

Zinc Oxide 40%

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 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, and 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

Other information

store at room temperature 15° - 30°C (59° - 86°F)

Inactive ingredients

BHA, Cod liver oil, Fragrance, Lanolin, Petrolatum, Talc, Water

Principal Display Panel - Carton Label

NDC 11527-058-41

Dr. Sheffield's

Made in the USA

Diaper Rash

Ointment

40% Zinc Oxide Skin Protectant

- Promotes healing
- Relieves chafing
- Paraben free

**Helps Treat and
Prevent Diaper Rash**

NET WT. 2 oz. (56g)



Principal Display Panel - Tube Label

SHEFFIELD PHARMACEUTICALS www.sheffield-pharmaceuticals.com New London, CT 06320 USA

Questions? 1-800-222-1087 Made in the USA

NDC 11527-058-41

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DR. SHEFFIELD DIAPER RASH

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	400 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
COD LIVER OIL (UNII: BBL281NWFG)	
LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	
TALC (UNII: 7SEV7J4R1U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-058-41	1 in 1 CARTON	01/09/2002	
1		56 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 final	part347	01/09/2002	

Labeler - Sheffield Pharmaceuticals LLC (151177797)**Establishment**

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-058)

Revised: 12/2019

Sheffield Pharmaceuticals LLC