

**PURE BABY DIAPER RASH- zinc oxide cream**  
**Fischer Pharmaceuticals 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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**Pure Baby Diaper Rash Cream**

***Drug Facts***

**Active Ingredients**

Zinc Oxide 12%

**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.

**Stop use and ask a doctor if** condition worsens or lasts more than 7 days.

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

**Directions**

- Change wet and solid diapers promptly
- Clean the diaper area and allow to dry
- Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diaper may be prolonged.

**Inactive Ingredients**

Bisabolol, Calendula Officinalis Flower Extract, Caprylic/Capric Triglyceride, Coco-Caprylate, Dunaliella Salina Extract, Ethylhexylglycerin, Globularia Alypum Leaf Extract, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Castor Oil, Magnesium Sulfate, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-3 Diisostearate, Potassium Sorbate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sodium Benzoate, Tocopherol, Water.

**Questions or Comments?**

**Call 1-888-553-6112 Mon-Fri**

**Manufactured by:**

Fischer Pharmaceuticals Ltd.  
Tel Aviv, POB 39071, Israel.

**PRINCIPAL DISPLAY PANEL - 113 g Tube Label**

***Dr. Fischer***<sup>®</sup>

**Pure  
baby**

**Diaper Rash Cream**

**100%**  
ORGANIC OILS

Helps Treat &  
Prevent

With  
**Natural**  
Origin Ingredients

**SCIENCE INSIDE**  
- **SCIENCE INSIDE** -

Hypoallergenic • Sensitive Tested

**NO**  
Fragrance, Parabens, SLS, SLES,  
Lanolin, Silicones, Paraffin, GMOs

Net Wt. 4 oz. (113 g.)

**FISCHER PHARMACEUTICALS**

## Diaper Rash Cream

100% ORGANIC OILS | 98% Natural Origin Ingredients

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Manufactured by:  
 Fischer Pharmaceuticals Ltd.  
 Tel Aviv, POB 39071, Israel.

Dr. Fischer SA / NV  
 Ave. Louise 149, Brussels 1050 Belgium.

www.Dr-Fischer.com  
 Made in Israel

7290016912463

585752 1071 62579

**Dr. Fischer - Tried & Tested**



# Pure

baby

## Diaper Rash Cream

100% ORGANIC OILS

With Natural Origin Ingredients

Hypoallergenic • Sensitive Tested

NO

Fragrance, Parabens, SLS, SLES, Lanolin, Silicones, Paraffin, GMOs

Net Wt. 4 oz. (113 g.)

**FISCHER PHARMACEUTICALS**

## PURE BABY DIAPER RASH

zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59886-414
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	40 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
LEVOMENOL (UNII: 24WE03BX2T)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Coco-Caprylate (UNII: 4828G836N6)	
DUNALIELLA SALINA (UNII: F4O1DKI9A6)	
Ethylhexylglycerin (UNII: 147D247K3P)	
GLOBULARIA CORDIFOLIA WHOLE (UNII: SD327VQ78H)	
Glycerin (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
Hydrogenated Castor Oil (UNII: ZF94AP8MEY)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Polyglyceryl-2 Dipolyhydroxystearate (UNII: 9229XJ4V12)	
Polyglyceryl-3 Diisostearate (UNII: 46P231IQV8)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
ALMOND OIL (UNII: 66YXD4DKO9)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Tocopherol (UNII: R0ZB2556P8)	
Water (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59886-414-32	113 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	01/01/2018	

**Labeler** - Fischer Pharmaceuticals Ltd (600158976)

## Establishment

Name	Address	ID/FEI	Business Operations
Fischer Pharmaceuticals Ltd		600410514	MANUFACTURE(59886-414)