ULTRASOL NATURE BABY SUNSCREEN- titanium dioxide, zinc oxide lotion 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.

Dr. Fischer ULTRASOL nature BABY Sunscreen Lotion SPF50

Drug Facts

Active Ingredients Purpose Titanium Dioxide 15.0%, Zinc Oxide 8.0%...... Sunscreen

Uses

- helps prevent sunburn higher SPF gives more sunburn protection
- helps protect the skin against the harmful effects of UVA and UVB rays
- retains SPF after 80 minutes of activity in the water or sweating

Warnings

For external use only

When using this product

avoid contact with the eyes. If contact occurs rinse thoroughly with water.

Stop use and ask a doctor if

rash or irritation develops and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- apply generously and evenly to all exposed areas before sun exposure
- reapply as needed or after towel drying, swimming, perspiring or vigorous activity
- children under 6 months of age: ask a doctor

Other Information

- may stain some fabrics
- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Inactive Ingredients

Aloe Barbadensis (Aloe Vera) Leaf Extract, Alumina, Aluminum Stearate, Avena Satina (Oat) Kernel Oil, C20-40 Acid, Calendula Officinalis Flower Oil, Camellia Sinensis Leaf Extract, Caprylic / Capric Triglyceride, Cetyl Dimethicone, Cetyl PEG/PPG 10/1 Dimethicone, Chamomile Oil, Coco Nucifera (Coconut) Oil, Cyclomethicone, Diazolidinyl Urea, Dimethicone, Ethylhexyl Palmitate, Fragrance, Hydrogenated Castor Oil, Isododecane, Methylparaben, Mineral Oil, Panthenol, Polyethylene, Polyhydroxystearic Acid, Propylene Glycol, Propylparaben, Sodium Chloride, Tocopheryl Acetate, Water.

Questions or Comments?

Call 1-877-212-1985 Mon-Fri

Dr. Fischer ULTRASOL

nature BABY Sunscreen Lotion SPF50

Broad Spectrum UVA and UVB Protection

Pediatrician Recommended

With Oatmeal and Aloe Vera

SCIENCE INSIDETM SUPERIOR SUN TECHNOLOGY

VERY WATER RESISTANT

Hypoallergenic

Non-Irritating

Ophthalmologically Tested

RECOMMENDED SKIN CANCER FOUNDATION

200 ML. 6.77 FL. OZ.

FISCHER PHARMACEUTICALS

Manufactured by:

Fischer Pharmaceuticals Ltd.

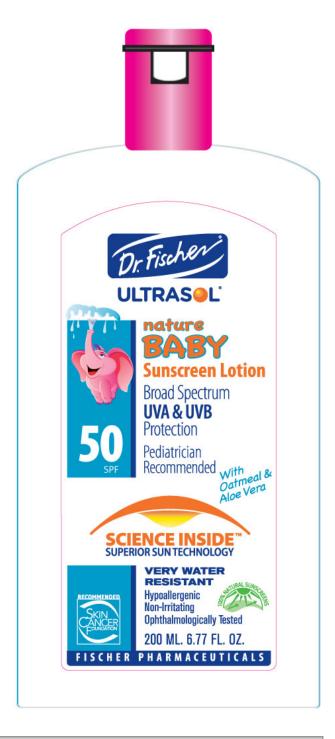
Bnei Brak, Israel, 51553

Made in Israel

www.dr-fischer.com

Dr. Fischer - Tried and Tested





ULTRASOL NATURE BABY SUNSCREEN

TOPICAL

titanium dioxide, zinc oxide lotion

Route of Administration

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59886-349

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dio xide	15 g in 100 g	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	8 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
Aluminum Stearate (UNII: U6 XF9 NP8 HM)	
Coconut Oil (UNII: Q9L0O73W7L)	
Methylparaben (UNII: A2I8C7HI9T)	
Panthenol (UNII: WV9CM0O67Z)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sodium Chloride (UNII: 451W47IQ8X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:59886-349-66	200 g in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/10/2010	

Labeler - Fischer Pharmaceuticals Ltd (600158976)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fischer Pharmaceuticals Ltd		600158976	manufacture	

Revised: 5/2010 Fischer Pharmaceuticals Ltd