# ULTRASOL NATURE BABY SUNSCREEN- titanium dioxide, 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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### Dr. Fischer ULTRASOL nature BABY Sunscreen Face Cream 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 Face Cream SPF50

Broad Spectrum UVA and UVB Protection

Pediatrician Recommended

SCIENCE INSIDE<sup>TM</sup> SUPERIOR SUN TECHNOLOGY

VERY WATER RESISTANT

Non-Irritating

Ophthalmologically Tested

RECOMMENDED SKIN CANCER FOUNDATION

This product is recommended by the American Skin Cancer Foundation as an effective UV sunscreen

Extra gentle for baby's delicate skin

Gentle Baby Sun Care and Protection

Hypoallergenic

Sensitive-Tested

Light Texture

Rapidly Absorbed

Natural Herbal Complex to Care for Baby's Skin: Oatmeal, Aloe Vera,

Chamomile and Calendula

Vitamin E and Green Tea antioxidant protection against free radicals

50 ML. 1.69 FL. OZ.

100% NATURAL SUNSCREENS

Manufactured by:

Fischer Pharmaceuticals Ltd.

Bnei Brak, Israel, 51553

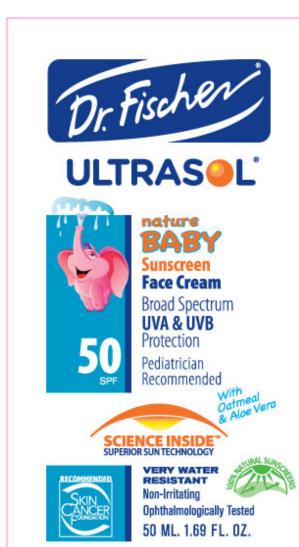
Made in Israel

www.dr-fischer.com

Fischer Pharmaceuticals

Dr. Fischer - Tried and Tested

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Bnei Brak, Israel, 51553 Made in Israel www.dr-fischer.com



FISCHER PHARMACEUTICALS

Pantone O21 Pantone 012 Pantone 2747

Pantone 313

Magenta

Black







### Extra gentle for baby's delicate skin

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### **Gentle Baby Sun Care** & Protection

- Hypoallergenic
- Sensitive-Tested
- Light Texture
- Rapidly Absorbed

**Natural Herbal Complex** to Care for Baby's Skin: Oatmeal, Aloe Vera, Chamomile & Calendula.

Vitamin E & Green Tea antioxidant protection against free radicals.





nature Sunscreen **Face Cream** 

**Broad Spectrum UVA & UVB** Protection

Pediatrician Recommended



FISCHER PHARMACEUTICALS



VERY WATER RESISTANT Hypoallergenic Non-Irritating Ophthalmologically Tested 50 ML. 1.69 FL. OZ.





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Manufactured by: Fischer Pharmaceuticals Ltd. Bnei Brak, Israel, 51553 Made in Israel www.dr-fischer.com



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Dr. Fischer - Tried & Tested

### FISCHER PHARMACEUTICALS

### Drug Facts (continued)

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## Pantone 2747 Pantone 021 Pantone 012 M C

### ULTRASOL NATURE BABY SUNSCREEN

titanium dioxide, zinc oxide cream

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59886-304

**TOPICAL** Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	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)	
Sodium Chloride (UNII: 451W47IQ8X)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0KO0R)	

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:59886-304-77	1 in 1 BOX		
1		50 g in 1 TUBE		

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