ULTRASOLSUNSCREEN NATURE BABY SUNSCREEN FACE CREAM SPF 45- avobenzone, octinoxate, octis alate, oxybenzone 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.

Dr. Fischer ULTRASOL nature BABY Sunscreen Face Cream SPF 45





Drug Facts

Active Ingredients

Purpose

Avobenzone 2.0%, Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 4.0%

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 Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis (Aloe Vera) Leaf Extract, Avena Sativa (Oat) Kernel Extract, Butylparaben, Calendula officinalis Flower Oil, Chamomilla Recutita (Matricaria) Extract, Chlorophenesin, Disodium EDTA, Ethylparaben, Fragrance, Glyceryl Stearate, Green Tea (Camellia Sinensis) Leaf Extract, lodopropynyl Butylcarbamate, Isopropyl Myristate, Methylparaben, Phenoxyethanol, Polyethylene, Potassium Cetyl Phosphate, Propylene Glycol, Propylparaben, Sodium Hydroxide, Stearic Acid, Stearyl Alcohol, Tocopheryl Acetate, Water.

Questions or Comments? Call 1-877-212-1985 Mon-Fri



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Manufactured by: Fischer Pharmaceuticals Ltd.

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



FISCHER PHARMACEUTICALS



Dr Fischer ULTRASOL
nature BABY
Sunscreen SPF 45
Face Cream
Broad Spectrum

UVA and UVB Protection

Pediatrician Recommended

With Oatmeal and Aloe Vera

SCIENCE INSIDETM SUPERIOR SUN TECHNOLOGY

VERY WATER RESISTANT

Ophthalmologically Tested

Non-Irritating

RECOMMENDED - SKIN CANCER FOUNDATION

50 ML. 1.69 FL. OZ.

(Back of the package):

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Bnei Brak, Israel, 51553

Made in Israel

www.dr-fischer.com

NO ANIMAL INGREDIENTS - NO ANIMAL TESTING

24m

FISCHER PHARMACEUTICALS

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avobenzone, octinoxate, octisalate, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59886-337
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	2 g in 100 g	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g	
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5 g in 100 g	
Oxybenzone (UNII: 9500S7VE0Y) (Oxybenzone - UNII:9500S7VE0Y)	Oxybenzone	4 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
Butylparaben (UNII: 3QPI1U3FV8)			
Chlorphenesin (UNII: 1670 DAL4SZ)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			

Ethylparaben (UNII: 14255EXE39)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
Isopropyl Myristate (UNII: 0 RE8K4LNJS)	
Methylparaben (UNII: A2I8C7HI9T)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0KO0R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59886-337-77	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	03/01/2010	

Labeler - Fischer Pharmaceuticals Ltd (600158976)

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

Revised: 1/2010 Fischer Pharmaceuticals Ltd