ULTRASOLSUNSCREEN KIDS SUNSCREEN LOTION- avobenzone, octinoxate, octisalate, oxybenzone 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 KIDS Sunscreen Lotion SPF45

Drug Facts

Active Ingredients Purpose Avobenzone 2.0%, Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 4.0% 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

Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Butylparaben, Chlorophenesin, Disodium EDTA, Ethylparaben, Fragrance, Glyceryl Stearate, Green Tea (Camellia Sinensis) Leaf Extract, Iodopropynyl 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



KIDS Sunscreen Lotion SPF45

Broad Spectrum UVA and UVB Protection

Pediatrician Recommended

Fun Melon Fragrance

SCIENCE INSIDETM - SUPERIOR SUN TECHNOLOGY

VERY WATER RESISTANT

Hypoallergenic

Sensitive Approved

RECOMMENDED - SKIN CANCER FOUNDATION

250 ML. 8.45 FL. OZ.

FISCHER PHARMACEUTICALS

(Back of Package):

Manufactured by:

Fischer Pharmaceuticals Ltd.

Bnei Brak, Israel, 51553

Made in Israel

www.dr-fischer.com

NO ANIMAL INGREDIENTS - NO ANIMAL TESTING

24m

Dr. Fischer - Tried and Tested

ULTRASOLSUNSCREEN KIDS SUNSCREEN LOTION

avobenzone, octinoxate, octisalate, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59886-309
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: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W)	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: I670 DAL4SZ)	

EDETATE DISO DIUM (UNII: 7FLD91C86K)	
Ethylparaben (UNII: 14255EXE39)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
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)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:59886-309-55	250 g in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	0 3/0 1/20 10		

Labeler - Fischer Pharmaceuticals Ltd (600158976)

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

Revised: 1/2010 Fischer Pharmaceuticals Ltd