

**ULTRASOL KIDS SUNSCREEN - avobenzone, octinoxate, octisalate, 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 KIDS Sunscreen SPF 45

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

Dr. Fischer ULTRASOL

KIDS Sunscreen Face Cream 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

50 ML. 1.69 FL. OZ.

Manufactured by:

Fischer Pharmaceuticals Ltd.

Bnei Brak, Israel, 51553

Made in Israel

www.dr-fischer.com

NO ANIMAL INGREDIENTS - NO ANIMAL TESTING

24m

FISCHER PHARMACEUTICALS

Dr. Fischer - Tried and Tested

Outdoor Care and Protection

Extra Skin-Friendly

Children's Sun Care

Light Texture

Rapidly Absorbed

Soothes and calms the skin with Chamomile

Vitamin E and Green Tea antioxidant protection against free radicals

Tested according to the most stringent international sunscreen standards

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



ULTRASOL®



KIDS
Sunscreen
Face Cream

Broad Spectrum
UVA & UVB
Protection
Pediatrician
Recommended

*Fruity
Melon
Fragrance*



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



FISCHER PHARMACEUTICALS



ULTRASOL KIDS SUNSCREEN

avobenzone, octinoxate, octisalate, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59886-327
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzene (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	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: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Butylparaben (UNII: 3QP1U3FV8)	
Chlorphenesin (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Ethylparaben (UNII: 14255EXE39)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Methylparaben (UNII: A218C7H9T)	
Phenoxyethanol (UNII: H1E492ZZ3T)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Stearyl Alcohol (UNII: 2KR89I4HIY)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59886-327-77	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