

ULTRASOLSUNSCREEN SUNSCREEN LOTION SPF45- avobenzene, 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 Sunscreen Lotion SPF45

Drug Facts

Active Ingredients

Purpose

Avobenzene 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



Over Print WHITE



Over Print WHITE

Dr. Fischer ULTRASOL
Sunscreen Lotion SPF45
Broad Spectrum

UVA and UVB Protection

Dermatologist Recommended

SCIENCE INSIDE™ 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 SUNSCREEN LOTION SPF45

avobenzone, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59886-322
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: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Butylparaben (UNII: 3QPI1U3FV8)	
Chlorphenesin (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Ethylparaben (UNII: 14255EXE39)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Methylparaben (UNII: A2B8C7H9T)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
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: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59886-322-55	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	03/01/2010	

Labeler - Fischer Pharmaceuticals Ltd (600158976)

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