ULTRASOLSUNSCREEN SUNSCREEN LOTION SPF 34- 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 Sunscreen Lotion SPF34

Dr. Fischer ULTRASOL

Sunscreen Lotion

SPF34

Broad Spectrum UVA and UVB Protection

Dermatologist Recommended

SCIENCE INSIDE^{TM} SUPERIOR SUN TECHNOLOGY

VERY WATER RESISTANT Hypoallergenic

Sensitive Approved

RECOMMENDED - SKIN CANCER FOUNDATION

125 ML. 4.22 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

Drug Facts

Active Ingredients	Purpose
Avobenzone 2.0%, Octinoxate 7.5%, Octisalate 3.0%, Oxybenzone 3.0%	Sunscreen

Uses

• helps prevent sunburn • higher SPF gives more sunburn protection
• helps protect the skin against the h armful 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 u s e 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 sun screens may reduce th e risks of skin aging, skin cancer, and other harmful effects of the sun.

Inactive Ingredients

Acrylates / C 10-30 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

ULTRASOLSUNSCREEN SUNSCREEN LOTION SPF 34

avobenzone, octinoxate, octisalate, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59886-319
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	3 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	3 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: A2I8C7HI9T)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59886-319-11	125 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

Revised: 2/2010 Fischer Pharmaceuticals Ltd