## ULTRASOL OIL-FREE 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.

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#### Dr. Fischer ULTRASOL OIL-FREE Sunscreen Face Cream 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

Dr. Fischer ULTRASOL

**OIL-FREE** 

Sunscreen Face Cream SPF45

Broad Spectrum UVA and UVB Protection

Dermatologist Recommended

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

FISCHER PHARMACEUTICALS

Dr. Fischer - Tried and Tested

Extra light for delicate face and neck areas

Extra light and Sun Protection

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





### **OIL-FREE**

### Sunscreen

**Face Cream** 

**Broad Spectrum** UVA & UVB Protection

<u>Dermatologist</u> Recommended





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Sunscreen

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Manufactured by: Fischer Pharmaceuticals Ltd. Bnei Brak, Israel, 51553 Made in Israel www.dr-fischer.com



FISCHER PHARMACEUTICALS

CMK Pantone 012c Pantone 021c Pantone 2747



#### ULTRASOL OIL-FREE SUNSCREEN

avobenzone, octinoxate, octisalate, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59886-338
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 Y0596 W) (Octisalate - UNII:4X49 Y0596 W)	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: 7FLD9 1C86K)	
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:59886-338-77	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	

Revised: 4/2010 Fischer Pharmaceuticals Ltd