

**ULTRASOL SUNSCREEN LOTION SPF 45- 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.*

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**Dr. Fischer ULTRASOL Sunscreen Lotion SPF45 125 ml**

**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**

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

Section Text

Dr. Fischer ULTRASOL

Sunscreen Lotion SPF 45

Broad Spectrum

UVA and UVB Protection

Dermatologist Recommended

Science Inside™ 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](http://www.dr-fischer.com)

NO ANIMAL INGREDIENTS - NO ANIMAL TESTING

24m

Dr. Fischer Tried and Tested



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Over Print WHITE

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Over Print WHITE

## ULTRASOL SUNSCREEN LOTION SPF 45

avobenzone, octinoxate, octisalate, oxybenzone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59886-355
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Avobenzon</b> e (UNII: G63QQF2NOX) (Avobenzon - UNII:G63QQF2NOX)	Avobenzon	2 g in 100 g
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5 g in 100 g
<b>Oxybenzon</b> e (UNII: 95OOS7VE0Y) (Oxybenzon - UNII:95OOS7VE0Y)	Oxybenzon	4 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Butylparaben</b> (UNII: 3QPIIU3FV8)	
<b>Chlorphenesin</b> (UNII: I670DAL4SZ)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>Ethylparaben</b> (UNII: 14255EXE39)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>Isopropyl Myristate</b> (UNII: 0RE8K4LNJS)	
<b>Methylparaben</b> (UNII: A2I8C7HI9T)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Stearyl Alcohol</b> (UNII: 2KR89I4HIY)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>Water</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59886-355-11	125 g in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2010	

**Labeler** - Fischer Pharmaceuticals Ltd. (600158976)**Establishment**

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