

CERAMIDE EYEWISH EYE SUNSCREEN SPF 10- octinoxate and oxybenzone cream
Elizabeth Arden, Inc

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.

BC0772

DESCRIPTION

Ceramide and botanical technology combine in one gentle all-around eye cream. This instantly moisturizing formula reduces the appearance of dark circles and fine lines, promotes firmer looking skin, soothes puffiness, and helps protect against future signs of aging due to sun exposure.

INDICATIONS AND USAGE

To Use: Pat gently all around eye area.

For Sunscreen Use: Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours.

Childre Under 6: Ask a doctor.

WARNINGS

Warnings:

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been show to prevent sunburn, not skin cancer or early skin aging.

For external use only.

Do not use on damaged or broken skin.

When using this product, keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

OTC - ACTIVE INGREDIENT

Active Ingredients: Octinoxate 6.00% , Oxybenzone 0.50%.

INACTIVE INGREDIENT

Other Ingredients: Water, Hamamelis Virginiana (Witch Hazel) Water, Dimethicone, Squalene, Butylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Glycerin, Caprylic/Capric/Stearic Triglyceride, Polymethyl Methacrylate, Cetyl Alcohol, Alcohol Denat., Ceramide 3, Ergothioneine, Avena Sativa (Oat) Bran, Centella Asiatica Extract, Cucumin Sativus (Cucumber) Fruit Extract, Echinacea Purpurea Extract, Ginkgo Biloba Leaf Extract, Morus Bombycis Root Extract, Pyrus Malus (Apple) Fruit Extract, Salvia Officinalis (Sage) Leaf Extract, Scutellaria Baicalensis Root Extract, Vitis Vinifera (Grape) Fruit Extratct, Vitin Vinifera (Grape) Seed Extract, Retinyl Linoleate, Tocopherol, Propylene Glycol, Phospholipids, Laureth-7, Beta-Glucan, C13-14 Isoparaffin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polyacrylamide, Triethanolamine, BHT, Sodium Metabisulfite, Sodium Sulfite, Disodium EDTA, Diazolidnyl Urea, Methyl Paraben, Phenoxyethanol.

DOSAGE & ADMINISTRATION

Pat around eye area.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

OTC - PURPOSE

Provides SPF 10 sun protection.

OTC - WHEN USING

Keep out of eyes.



Elizabeth Arden

NEW YORK

Ceramide Eye Wish Eye Cream Sunscreen SPF 10

Ceramide and botanical technology combine in one gentle all-around eye cream. This instantly moisturizing formula reduces the appearance of dark circles and fine lines, promotes firmer looking skin, soothes puffiness and helps protect against future signs of aging due to sun exposure.

To use: Pat gently around eye area.

Clinically, dermatologist and allergy tested.
Ophthalmologist tested.

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elizabetharden.com

Drug Facts (continued)

Other Information

- Protect this product from excessive heat and direct sun

Questions or comments?

- Call toll free 1-800 326-7337

Drug Facts (continued)

in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

■ For external use only

■ **Do not use** on damaged or broken skin

■ **When using this product** keep out of eyes. Rinse with water to remove.

■ **Stop use and ask a doctor** if rash occurs

■ **Keep out of reach of children.**

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For Sunscreen Use:

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - at least every 2 hours
- Children under 6 months: Ask a doctor.

Inactive Ingredients

WATER/AQUA/EAU, HAMAMELIS VIRGINIANA (WITCH HAZEL) WATER, DIMETHICONE, SQUALENE, BUTYLENE GLYCOL, GLYCERYL STEARATE, PEG-100 STEARATE, GLYCERIN, CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE, POLYMETHYL METHACRYLATE, CETYL ALCOHOL, ALCOHOL DENAT., CERAMIDE 3, ERGOTHIONEINE, AVENA SATIVA (OAT) BRAN, CENTELLA ASIATICA EXTRACT, CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT, ECHINACEA PURPUREA EXTRACT, GINKGO BILOBA LEAF EXTRACT, MORUS BOMBYCIS ROOT EXTRACT, PYRUS MALUS (APPLE) FRUIT EXTRACT, SALVIA OFFICINALIS (SAGE) LEAF EXTRACT, SAXIFRAGA SARMENTOSA EXTRACT, SCUTELLARIA BAICALENSIS ROOT EXTRACT, VITIS VINIFERA (GRAPE) FRUIT EXTRACT, VITIS VINIFERA (GRAPE) SEED EXTRACT, RETINYL LINOLEATE, TOCOPHEROL, PROPYLENE GLYCOL, PHOSPHOLIPIDS, LAURETH-7, BETA-GLUCAN, C13-14 ISOPARAFFIN, ACRYLATES/ C10-30 ALKYL ACRYLATE CROSSPOLYMER, POLYACRYLAMIDE, TRIETHANOLAMINE, BHT, SODIUM METABISULFITE, SODIUM SULFITE, DISODIUM EDTA, DIAZOLIDINYL UREA, METHYLPARABEN, PHENOXYETHANOL.

Drug Facts

Active Ingredients	Purpose
OCTINOXATE 6.00%.....	Sunscreen
OXYBENZONE 0.50%.....	Sunscreen

Uses

- Helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time



CERAMIDE EYEWISH EYE SUNSCREEN SPF 10

octinoxate and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-0772
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.852 g in 14.2 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.071 g in 14.2 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
HAMAMELIS VIRGINIANA LEAF WATER (UNII: 8FP93ED6H2)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SQUALENE (UNII: 7QWM220FJH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
GLYCERIN (UNII: PDC6A3C0OX)
CETYL ALCOHOL (UNII: 936JST6JCN)
ALCOHOL (UNII: 3K9958V90M)
TROLAMINE (UNII: 9O3K93S3TK)
OXYBENZONE (UNII: 95OOS7VE0Y)
TOCOPHEROL (UNII: R0ZB2556P8)
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)
WINE GRAPE (UNII: 3GOV20705G)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
CUCUMBER (UNII: YY7C30VXJT)
RETINYL LINOLEATE (UNII: 61911N8D6W)
EDETATE DISODIUM (UNII: 7FLD91C86K)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
LAURETH-7 (UNII: Z95S6G8201)
CERAMIDE 3 (UNII: 4370DF050B)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
SODIUM SULFITE (UNII: VTK01UQK3G)
SALVIA OFFICINALIS FLOWERING TOP (UNII: 48JCS720FN)
GINKGO (UNII: 19FUJ2C58T)
APPLE (UNII: B423VGH5S9)
MORUS AUSTRALIS ROOT (UNII: 1VL55O45RF)
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)
METHYLPARABEN (UNII: A2I8C7HI9T)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
OAT BRAN (UNII: KQX236OK4U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
ECHINACEA PURPUREA (UNII: QI7G114Y98)
VITIS VINIFERA SEED (UNII: C34U15ICXA)
ERGOTHIONEINE (UNII: BDZ3DQM98W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0772-1	1 in 1 BOX		
1	NDC:67938-0772-2	14.2 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/16/2006	

