

ANTI-AGING COMPLEX EYE TREATMENT MERLE NORMAN- octinoxate, zinc oxide lotion

Merle Norman Cosmetics

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.

Anti-Aging Complex Eye Treatment Broad Spectrum SPF 15

Active ingredients Purpose

Octinoxate 7.4% Sunscreen

Zinc Oxide 6.5% Sunscreen

Uses

helps prevent sunburn

If used as directed with other sun protection measures (See Directions) decreases the risk of skin cancer and early skin aging caused by the sun.

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

Stop use and ask a doctor if rash occurs

Warnings

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.

Directions

For sunscreen

- apply liberally and evenly 15 minutes before sun exposure
- use a water resistant sunscreen if swimming
- reapply at least every 2 hours

Sun Protection Measures. Spending time in the sun increase your risk of skin cancer and early skin aging. To decrease this risk of skin cancer, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including"

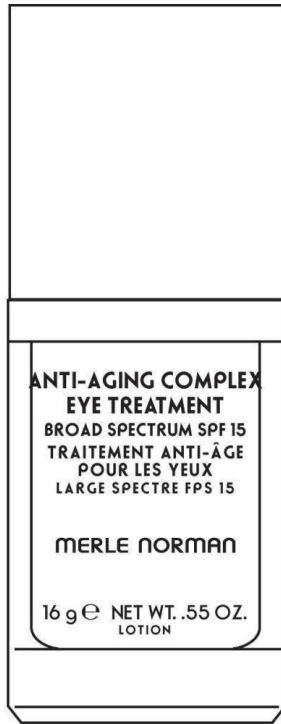
- limit time in the sun, especially from 10 a.m.-2p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

children under six months: Ask a doctor

Inactive ingredients

Water (Aqua), Glycerin, Butyrospermum Parkii (Shea Butter), Squalane, Cyclopentasiloxane, Isononyl Myristate, Pentylene Glycol, C12-15 Alkyl Benzoate, Isopropyl Myristate, Cetearyl Alcohol, Glyceryl Stearate, Nylon-12, PEG-100 Stearate, Cetareth-20, Polyacrylamide, Acetyl Octapeptide-3, Acetylglycyltryptophyl Diphenylglycine, Palmitoyl Tetrapeptide-7, Medicago Sativa (Alfafa) Seed Extract, Euphrasia Officinalis Extract, Retinyl Palmitate, Ascorbyl Palmitate, Tocopheryl Acetate, Dimethicone Crosspolymer, Cyclomethicone,

Cyclotetrasiloxane, Ethylhexyl palmitate, Propylene Glycol, Butylene Glycol, Caprylyl Glycol, Sodium Hyaluronate, Hesperidin Methyl Chalcone, Ceramide-2, Hydrolyzed Lupine Protein, Hydrolyzed Vegetable Protein, Adenosine Triphosphate, Acetyl Tyrosine, Phospholipids, C13-14 Isoparaffin, Proline, Tribehenin, Triethoxycaprylylsilane, PEG-30 Dipolyhydroxypropyl, Laureth-7, Steareth-20 PEG-10 Rapeseed Sterol, Xanthan Gum, Hydroxypropyl Cyclodextrin, PVP, BHT Silica, Silica Dimethyl Silylate, Trisodium EDTA, Benzyl Alcohol, Tropolone Chlorphenesin, Phenoxyethanol, Titanium Dioxide, Mica.



**ANTI-AGING COMPLEX
EYE TREATMENT**
BROAD SPECTRUM SPF 15
TRAITEMENT ANTI-ÂGE
POUR LES YEUX
LARGE SPECTRE FPS 15

MERLE NORMAN

16 g e NET WT. .55 OZ.
LOTION

Dermatologist Tested.

Directions: Apply around eye area in a patting motion.

Mode d'emploi: Appliquez en tapotant le contour de l'œil.

Warnings: For external use only. Not to be swallowed. Avoid contact with eyes. Stop use and ask a doctor if rash or irritation develops or lasts. Keep out of reach of children.

Avertissement: Pour usage externe uniquement. Ne pas avaler. Éviter le contact avec les yeux. Arrêter l'utilisation et consulter un médecin si une éruption ou une irritation se développe ou dure. Ne pas laisser à la portée des enfants.

Active (Medicinal) Ingredients (w/w): Octinoxate, 7.4 %.; Zinc Oxide, 6.5%.



MANUFACTURED BY: MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045 MADE IN USA
IMPORTED BY: MERLE NORMAN COSMETICS
TORONTO, ONTARIO M1X 1E7

NO COATING

NO COATING

NO COATING

Drug Facts

Active ingredients

Octinoxate 7.4%
Zinc Oxide 6.5%

Purpose

Sunscreen
Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

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

Directions

- For sunscreen use:
 - apply liberally and evenly 15 minutes before sun exposure
 - use a water resistant sunscreen if swimming or sweating
 - reapply at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive ingredients: Water (Aqua), Glycerin, Butyrospermium Parkii (Shea Butter), Squalane, Cyclopentasiloxane, Isononyl Isononanoate, Pentylene Glycol, C12-15 Alkyl Benzoate, Isopropyl Myristate, Cetearyl Alcohol, Glyceryl Stearate, Nylon-12, PEG-100 Stearate, Ceteareth 20, Polyacrylamide, Acetyl Octapeptide-3, Acetylarginyltryptophyl Diphenylglycine, Palmitoyl Tripeptide-38, Dipptide-2, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Medicago Sativa (Alfalfa) Seed Extract, Euphrasia Officinalis Extract, Retinyl Palmitate, Ascorbyl Palmitate, Tocopheryl Acetate, Dimethicone Crosspolymer, Cyclomethicone, Cyclotetrasiloxane, Ethylhexyl Palmitate, Propylene Glycol, Butylene Glycol, Caprylyl Glycol, Sodium Hyaluronate, Hesperidin Methyl Chalcone, Caramida 2, Hydrolyzed Lucina Protein, Hydrolyzed Vegetable Protein, Adenosine Trichoschate, Acetyl Tyrosine. ▶



Anti-Aging Complex Eye Treatment
Broad Spectrum

Merle Norman
established in Los Angeles since 1931

16 g Net Wt. .55 oz

ANTI-AGING COMPLEX EYE TREATMENT MERLE NORMAN

octinoxate, zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:57627-150

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.18 g in 16 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.04 g in 16 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SHEA BUTTER (UNII: K49155WL9Y)	
SQUALANE (UNII: GW89575KF9)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
NYLON-12 (UNII: 446U8J075B)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
ACETYL OCTAPEPTIDE-3 (UNII: 8K14HJF88S)	
VALYLTRYPTOPHAN (UNII: 3G64B4AFQN)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
ALFALFA SEED (UNII: 67PHZ58858)	
EUPHRASIA STRICTA (UNII: C9642I91WL)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HESPERIDIN METHYLCHALCONE (UNII: 4T2GVA922X)	
CERAMIDE 2 (UNII: C04977SRJ5)	
ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE)	
N-ACETYLTYSOSINE (UNII: DA8G610ZO5)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
PROLINE (UNII: 9DLQ4CIU6V)	

TRIBEHENIN (UNII: 8OC9U7TQZ0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
LAURETH-7 (UNII: Z95S6G8201)	
STEARETH-20 (UNII: L0Q8IK9E08)	
PEG-10 RAPESEED STEROL (UNII: 258O76T85M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TROPOLONE (UNII: 7L6DL16P1T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-150-02	1 in 1 CARTON	11/09/2012	
1	NDC:57627-150-01	16 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/09/2012	

Labeler - Merle Norman Cosmetics (008479388)

Registrant - Merle Norman Cosmetics (008479388)

Establishment

Name	Address	ID/FEI	Business Operations
Merle Norman Cosmetics		008479388	manufacture(57627-150)