

TOTAL EYE 3-IN-1 RENEWAL THERAPY SPF 35- titanium dioxide and zinc oxide liquid Colorescience

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.

Total Eye™ 3-In-1 Renewal Therapy SPF 35

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 7.9%	Sunscreen
Zinc Oxide 6.7%	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

- Apply liberally 15 minutes before sun exposure. Works best on moisturized skin.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months: ask a doctor.

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.

Inactive Ingredients

Aqua/Water, Hydrogenated Polyisobutene, Cyclopentasiloxane, Caprylic/Capric Triglyceride, Lauryl Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Glycerin, Panthenol, Mica, Dimethicone Crosspolymer, Albizia Julibrissin Bark Extract, Sea Water, Sorbitol, Jojoba Esters, Sodium Hyaluronate, Palmitoyl Tripeptide-5, Tremella Fuciformis Sporocarp Extract, Hydrolyzed Algin, Ascophyllum Nodosum Extract, Betaine, Dunaliella Salina Extract, Asparagopsis Armata Extract, Sucrose, Darutoside, Pantolactone, Tocopherol, Sodium Chloride, Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Polyhydroxystearic Acid, Glyceryl Behenate/Eicosadioate, Dimethicone, Lauroyl Lysine, Dimethiconol, Ethylhexylglycerin, Triethoxycaprylylsilane, Alumina, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Citric Acid, Iron Oxides (CI 77491, CI 77492, CI 77499)

Other Information

Protect this product from excessive heat and direct sun.

Questions or comments?

Call toll free 866.426.5673

Dist. in USA by **colorescience**[®]
Carlsbad, CA 92011

PRINCIPAL DISPLAY PANEL - 7 mL Tube Carton

colorescience[®]

TOTAL
EYE[™]

3-IN-1 RENEWAL
THERAPY

Corrects dark circles

Brightens and depuffs

Smooths fine lines
and wrinkles

35
Broad Spectrum
SPF 35 Sunscreen
PA+++

0.23 fl. oz. / 7 mL

OPEN

Ophthalmologist Reviewed:

- + Safe for use around the eye area
- + Safe for contact lens wearers
- + Safe for sensitive eyes

How to Use

Dispense half a pump to the applicator tip and dot around both eyes. Smooth product over the entire orbital region ensuring even coverage from under eye to brow, including eye lids. Blend with fingertips for seamless finish. Recommended for use twice daily. Can be worn overnight. Store at room temperature.



For USA only

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Titanium Dioxide 7.9%.....Sunscreen	
Zinc Oxide 6.7%.....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 ■ Apply liberally 15 minutes before sun exposure. Works	

For USA only

Drug Facts (Cont.)
Inactive Ingredients
Mica, Dimethicone Crosspolymer, Albizia Julibrissin Bark Extract, Sea Water, Sorbitol, Jojoba Esters, Sodium Hyaluronate, Palmitoyl Tripeptide-5, Tremella Fuciformis Sponcarp Extract, Hydrolyzed Algin, Ascophyllum Midosum Extract, Betaine, Dunaliella Salina Extract, Asparagopsis Armata Extract, Sucrose, Darutoside, Pantolactone, Tocopherol, Sodium Chloride, Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Polyhydroxystearic Acid, Glyceryl Behenate/Eicosadiolate, Dimethicone, Lauryl Lysine, Dimethiconol, Ethylhexylglycerin, Triethoxycaprylylsilane, Alumina, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Citric Acid, Iron Oxides (CI 77491, CI 77492, CI 77499)

Ingredients (EU) (Cont.)

Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Polyhydroxystearic Acid, Glyceryl Behenate/Eicosadiolate, Dimethicone, Lauryl Lysine, Dimethiconol, Ethylhexylglycerin, Triethoxycaprylylsilane, Alumina, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Citric Acid [CI 77491, CI 77492, CI 77499, CI 77891]

How to Use (EU)

Do not stay too long in the sun, even while using a sunscreen product. Keep babies and young children out of direct sunlight. Over-exposure to the sun is a serious health threat. Reducing the quantity of sunscreen product applied will lower the level of protection significantly. Generously apply sunscreen products before sun exposure. Keep out of eyes. Stop use and ask a doctor if adverse reaction occurs.

The Eyes Have It
With powerful clinical ingredients, Total Eye™ 3-in-1 Renewal Therapy provides a rested, youthful appearance by visibly improving signs of skin aging. The appearance of dark circles, puffiness, fine lines, and wrinkles are minimized while potent hydration helps restore the health of the delicate eye area. 100% mineral sunscreen provides chemical-free SPF 35 defense against photoaging.

Experience the confidence & ease of Colorescience®

- + Trusted and personally used by thousands of physicians.
- + 365-day defense from UV rays and environmental stressors.

Discover our full line of uncompromising,

best on moisturized skin. ■ Reapply at least every 2 hours ■ Use a water resistant sunscreen if swimming or sweating ■ Children under 6 months: ask a doctor.

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.

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Ingredients (EU)
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colorescience®
TOTAL EYE™

3-IN-1 RENEWAL THERAPY
Corrects dark circles
Brightens and depuffs
Smooths fine lines and wrinkles

health-forward
formulas designed
to fit your life at
colorescience.com

Inactive Ingredients
Aqua/Water, Hydrogenated
Polyisobutene, Cyclopentasiloxane,
Caprylo/Capric Triglyceride,
Lauryl Polyglyceryl-3
Polydimethylsilyloxyethyl
Dimethicone, Glycerin, Panthenol,

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Sodium Hyaluronate, Palmitoyl
Tripeptide-5, Tremella Fuciformis
Sporocarp Extract, Hydrolyzed Algin,
Ascochylium Nodosum Extract,
Betaine, Dunaliella Salina Extract,
Asparagopsis Armata Extract,
Sucrose, Dantrolene, Pantholactone,
Tocopherol, Sodium Chloride,

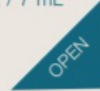
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Dist. in USA by colorescience®
Carlsbad, CA 92011
Made in USA
1709131R1

BIOBUS
Rue de la Croixière, 10A
BE-7170.MANAGE

35 Broad Spectrum
SPF 35 Sunscreen
PA+++

0.23 fl. oz. / 7 mL



TOTAL EYE 3-IN-1 RENEWAL THERAPY SPF 35

titanium dioxide and zinc oxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68078-024
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	79 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	67 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Glycerin (UNII: PDC6A3C0OX)	
Panthenol (UNII: WV9CM0O67Z)	
Mica (UNII: V8A1AW0880)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ALBIZIA JULIBRISSIN BARK (UNII: 0J9G6W44DV)	
Sorbitol (UNII: 506T60A25R)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
Palmitoyl Tripeptide-5 (UNII: 2A3916MQHO)	
ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)	
Betaine (UNII: 3SCV180C9W)	
DUNALIELLA SALINA (UNII: F401DKI9A6)	

ASPARAGOPSIS ARMATA (UNII: 2936KN6IIG)
Sucrose (UNII: C151H8M554)
Darutoside (UNII: EG8ODI0780)
PANTOLACTONE, (+/-)- (UNII: IID733HD2M)
Tocopherol (UNII: R0ZB2556P8)
Sodium Chloride (UNII: 451W47IQ8X)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)
Glyceryl Behenate/Eicosadioate (UNII: 73CJJ317SR)
Dimethicone (UNII: 92RU3N3Y1O)
Lauroyl Lysine (UNII: 113171Q70B)
Ethylhexylglycerin (UNII: 147D247K3P)
Triethoxycaprylsilane (UNII: LDC331P08E)
ALUMINUM OXIDE (UNII: LM26O6933)
Phenoxyethanol (UNII: HIE492ZZ3T)
Potassium Sorbate (UNII: 1VPU26JZZ4)
Sodium Benzoate (UNII: OJ245FE5EU)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68078-024-01	1 in 1 CARTON	01/19/2018	
1		7 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68078-024-02	0.5 mL in 1 PACKET; Type 0: Not a Combination Product	01/19/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/19/2018	

Labeler - Colorescience (128731929)