

TRIENELLE SKINCARE INSTANT ILLUSION DAILY RENEWAL CREME- octinoxate 5%, oxybenzone 4.5%, avobenzone 3% cream
NewMarket Health Products LLC

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.

Trienelle Skincare Instant Illusion Daily Renewal Creme

Drugs Facts

☐Active Ingredient

☐Octinoxate 5.0%

Oxybenzone 4.5%

Avobenzone 3.0%

☐Purpose

☐Sunscreen

☐Uses

- ☐Helps prevent sunburn
- Higher SPF gives more sunburn protection

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

☐Directions

- ☐Apply cream evenly twice daily to face, neck, and other exposed areas before exposure to the sun.
- Children under 6 months of age: 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 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
 - reapply at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating.

Water, Glycerin, C12-15 Alkyl Benzoate, Phenyl Trimethicone, Cyclopentasiloxane, Polydodecanamideaminum Triadiphenylethanesulfonate, Tocotrienols, Dimethicone, PEG-100 Stearate, Glyceryl Stearate, Cetearyl Alcohol, Cetyl Alcohol, Vaccinium Myrtillus Fruit and Leaf Extract, Chlorella Vulgaris Extract, Ganoderma Lucidum (Mushroom) Stem Extract, Trametes Versicolor Extract, Saccharum Officinarum (Sugar Cane) Extract, Acer Saccharum (Sugar Maple) Extract, Citrus Aurantium Dulcis Fruit Extract, Citrus Limon Extract, Palmitoyl Pentapeptide-4, Superoxide Dismutase, Stevia Rebaudiana Extract, Foeniculum Vulgare Extract, Hydrolyzed Algin, Pryus Malus Extract, Salix

Alba (Willow) Flower Extract, Colostrum, Melatonin, Sea Water, Phospholipids, Butylene Glycol, Triaccontanyl PVP, Phenoxyethanol, Xanthan Gum, Ceteareth-20, Carbomer, Polysorbate-20, Polyvinylalcohol Crosspolymer, Methylparaben, Butylparaben, Propylparaben, Ethylparaben, Tetrasodium EDTA, Triethanolamine

☐ **Other Information**

- ☐ **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.
- Protect the product in this container from excessive heat and direct sun.

Distributed by

Trienelle Skincare, Inc.

702 Cathedral St.

Baltimore, MD 21201

1-800-539-5195

www.trienelle.com

Trienelle Skincare

Instant Illusion

Daily Renewal Creme

WITH TOCALLURÉ RESTORATION COMPLEX

Broad Spectrum SPF 15

Formulated to: Instantly diminish ☐ the appearance of lines and wrinkles, and ☐ **visibly rejuvenate** ☐ the skin to reduce the signs of aging

Net. 50 ml (1.7 fl oz)

ADVANCED SKIN CARE
MADE SIMPLE

Drug Facts

Active Ingredient	Purpose
Octinoxate 6.0%	Sunscreen
Oxybenzone 4.5%	
Avobenzone 3.0%	

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection

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

Directions

- Apply cream evenly twice daily to the face, neck, and other exposed areas before exposure to the sun
- Children under 6 months of age: 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 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
 - reapply at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating.

Inactive Ingredients:

Water, Glycerin, C12-15 Alkyl Benzoate, Phenyl Trimethicone, Cyclopentasiloxane, Polydimethylsiloxane, Tris(trimethylgermyl)trisulfate, Tocopherols, Dimethicone, PEG-100 Stearate, Glyceryl Stearate

Drug Facts (continued)

Inactive Ingredients:

Cetyl Alcohol, Cetyl Alcohol, Vaccinium Myrtillus Fruit and Leaf Extract, Chlorella Vulgaris Extract, Ganoderma Lucidum (Mushroom) Stem Extract, Trieterep Vericolor Extract, **Saccharum Officinarum (Sugar Cane) Extract**, Acer Saccharum (Sugar Maple) Extract, Citrus Aurantium Dulcis Fruit Extract, Citrus Limon Extract, Palmitoyl Pentapeptide-4, Superoxide Dismutase, Stevia Rebaudiana Extract, Foeniculum Vulgare Extract, Hydrolyzed Algin, Pyrus Malus Extract, Salix Alba (Willow) Flower Extract, Coptis Root, Melatonin, Sasa Weltzii, Phospholipids, Butylene Glycol, Triacetin, PVP, Phenoxyethanol, Xanthan Gum, Ceteareth-20, Carbomer, Polysorbate-20, Polyvinyl Alcohol Crosspolymer, Methylparaben, Butylparaben, Propylparaben, Ethylparaben, Tetrasodium EDTA, Triethanolamine

Other Information

- **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.
- Protect the product in this container from excessive heat and direct sun.



Trienelle® Skincare

Instant Illusion®

Daily
Renewal
Creme

WITH TOCALLURÉ
RESTORATION COMPLEX
Broad Spectrum SPF 15

Formulated to:

Instantly diminish the appearance of lines and wrinkles, and visibly rejuvenate the skin to reduce the signs of aging

Net. 50 ml (1.7 fl oz)

The appearance of fine lines, imperfections and wrinkles seemingly fade away with Instant Illusion. It is the shadows cast within wrinkles that cause them to stand out. Trienelle's light control technology puts light within these shadows, creating the illusion that a decade has been magically brushed away.

Meanwhile, Trienelle is promoting younger-looking skin. Formulated by a physician-led team of skin care experts, Trienelle rejuvenates the skin with antioxidants, botanical extracts and beauty-enhancing compounds.

This product:

- Helps prevent sunburn
- Provides moderate protection against sunburn
- Provides broad spectrum protection from UVA and UVB rays
- Higher SPF gives more sunburn protection

Distributed by
Trienelle Skincare, Inc.
702 Cathedral St.
Baltimore, MD 21201
1-800-539-5195
www.trienelle.com

670SILL58

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U.S. Pat. No. 6,492,326

octinoxate 5%, oxybenzone 4.5%, avobenzone 3% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50972-455
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.5 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TOCOTRIENOLS (UNII: KP2MW85SSQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
VACCINIUM MYRTILLUS FRUITING TOP (UNII: QT6362QVN8)	
VACCINIUM MYRTILLUS LEAF (UNII: Y4U591OU70)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
GANODERMA LUCIDUM STEM (UNII: U8PA41532G)	
TRAMETES VERSICOLOR FRUITING BODY (UNII: 4C900477MT)	
SUGARCANE (UNII: 81H2R5AOH3)	
ACER SACCHARUM WHOLE (UNII: KEG5092LU9)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON (UNII: 24RS0A988O)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
SUPEROXIDE DISMUTASE (CU-ZN) SACCHAROMYCES CEREVISIAE (UNII: ZQP6EKT6WD)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
FOENICULUM VULGARE WHOLE (UNII: J1UK54JBGH)	
LAMINARIA DIGITATA HYDROLYZED ALGINIC ACID (UNII: 9E3P882579)	
APPLE (UNII: B423VGH5S9)	
SALIX ALBA FLOWER (UNII: 905Y746BSW)	
BOS TAURUS COLOSTRUM (UNII: S256WJ3OFQ)	
MELATONIN (UNII: JL5DK93RCL)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCINE MAX WHOLE (UNII: NID9NUV93F)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
XANTHAN GUM (UNII: TTV12P4NEE)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
CARBOMER 940 (UNII: 4Q93RCW27E)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
NYLON-12 (UNII: 446U8J075B)
BLANCOPHOR R (UNII: G8YVL0WOTF)
METHYLPARABEN (UNII: A2I8C7HI9T)
BUTYLPARABEN (UNII: 3QP1IU3FV8)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
ETHYLPARABEN (UNII: 14255EXE39)
EDETATE SODIUM (UNII: MP1J8420LU)
TROLAMINE (UNII: 9O3K93S3TK)

Product Characteristics

Color	white (off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50972-455-01	1 in 1 BOX		
1		50 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/30/2014	

Labeler - NewMarket Health Products LLC (828825989)

Establishment

Name	Address	ID/FEI	Business Operations
Biogenesis Labs		069117328	manufacture(50972-455)