

ADVANCED ANTI-WRINKLE THERAPY CICATRICURE- avobenzone 3%, octinoxate 7.5%, octisalate 5%, octocrylene 2.7%, oxybenzone 4% cream

Genomma Lab

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.

Active ingredients Purpose

Avobenzone 3%.....Sunscreen

Octinoxate 7.5%.....Sunscreen

Octisalate 5%.....Sunscreen

Octocrylene 2.7%.....Sunscreen

Oxybenzone 4%.....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 immediately

Directions

For sunscreen use: • apply generously and evenly 15 minutes before sun exposure. Reapply at least every

2 hours • use a water resistant sunscreen if swimming or sweating. **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 factor of 15 or higher and other skin protection measures including:

- limit time in the sun, especially from 10am to 2pm
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Inactive ingredients

Water

Glycerin

Dimethicone

Ethylhexyl Methoxycrylene

Neopentyl Glycol Diheptanoate

Glyceryl Stearate

Butylene Glycol

Isostearyl Neopentanoate

PPG-2 Isoceteth-20 Acetate

Polymethyl Methacrylate

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer

Bakuchiol

Retinyl Palmitate

Tocopheryl Acetate

Bisabolol

Cetearyl Alcohol

Sorbitan Oleate

Retinol

Hydroxypinacolone Retinoate

Myristoyl Nanapeptide-3

Palmitoyl Oligopeptide

Palmitoyl Tetrapeptide-7

Tocopherol

Sodium Ascorbate

Sodium Hyaluronate

Caprylic/Capric Triglyceride

Dimethicone Crosspolymer

Acrylates/C10-30 Alkyl Acrylate Crosspolymer

Behenyl Alcohol

Sodium Lactate

Ethylhexylglycerin

Isohexadecane

Polysorbate 80

Polysorbate 20

Dimethyl Isosorbide

Xanthan Gum

Carbomer

Disodium EDTA

Sodium Hydroxide

Pentylene Glycol

Chlorphenesin

Phenoxyethanol

Caprylyl Glycol

Citric Acid

Potassium Sorbate

Fragrance

Drug Facts

Active ingredients	Purpose
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Directions
 For sunscreen use: • apply generously and evenly 15 minutes before sun exposure. Reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating. 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 factor of 15 or higher and other skin protection measures including:
 • limit time in the sun, especially from 10am to 2pm
 • wear long-sleeved shirts, pants, hats and sunglasses
 • children under 6 months of age: ask a doctor

Other information
 • protect protect from excessive heat and direct sun
 • may stain some fabrics

Inactive ingredients
 Water, Glycerin, Dimethicone, Ethylhexyl Methoxycrylene, Neopentyl Glycol Diheptanoate, Glyceryl Stearate, Butylene Glycol, Isostearyl Neopentanoate, PPG-2 Isoceteth-20 Acetate, Polymethyl Methacrylate, Acrylamide/Sodium Acryloyldimethylsulfate Copolymer, Bakuchiol, Retinyl Palmitate, Tocopheryl Acetate, Bisabolol, Cetearyl Alcohol, Sorbitan Oleate, Retinol, Hydroxypropylcellulose, Retinoate, Myristoyl Nonapeptide-3, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Tocopherol, Sodium Ascorbate, Sodium Hyaluronate, Caprylic/Capric triglyceride, Dimethicone Crosspolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Behenyl Alcohol, Sodium Lactate, Ethylhexylglycerin, Isohexadecane, Polysorbate 80, Polysorbate 20, Dimethyl Isosorbide, Xanthan Gum, Carbomer, Disodium EDTA, Sodium Hydroxide, Pentylene glycol, Chlorphenesin, Phenoxyethanol, Caprylyl Glycol, Citric Acid, Potassium Sorbate, Fragrance

Questions
 Call toll free 1-877-99-GENOM (43666)
 Monday to Friday, 8am to 6pm, Central time

Distributed by / Distribuido por:
 Genomma Lab USA Inc.
 Houston, TX 77027

2CCCF34EW11

Datos del medicamento

Principios activos	Propósito
Avobenzone 3 %	Filtro solar
Octinoxato 7.5 %	Filtro solar
Octisalato 5 %	Filtro solar
Octocrieno 2.7 %	Filtro solar
Oxibenzona 4 %	Filtro solar

Usos
 • ayuda a prevenir las quemaduras solares
 • si se usa según lo indicado con otras medidas de protección solar (ver Instrucciones), disminuye el riesgo de cáncer de piel y el envejecimiento prematuro de la piel debido al sol

Precauciones
 Para uso externo únicamente
 No aplicar sobre la piel dañada o herida
 Al usar este producto evitar el contacto con la zona de los ojos. Enjuagar con agua para retirar
 Suspender el uso y consultar al médico si aparecen sarpullidos
 Mantener fuera del alcance de los niños. Si se traga, buscar ayuda médica o comunicarse con un centro de toxicología de inmediato.

Instrucciones
 Para usar como filtro solar: • aplicar de forma uniforme y abundante 15 minutos antes de exponerse al sol • repetir la aplicación cada 2 horas • usar un filtro solar resistente al agua en caso de nadar o transpirar. Medidas de protección contra el sol: Pasar tiempo al sol aumenta el riesgo de cáncer de piel y envejecimiento prematuro. Para disminuir este riesgo, use regularmente un filtro solar con factor FPS 15 de amplio espectro o mayor y otras medidas de protección de la piel, por ejemplo: • limitar la exposición al sol, especialmente desde las 10:00 a.m. hasta las 2:00 p. m. • usar camisas de manga larga, pantalones, sombrero y anteojos de sol • bebés menores de 6 meses: consultar al médico

Otra información
 • proteger del calor excesivo y los rayos directos del sol
 • puede manchar algunas telas

Excipientes
 Agua, glicerina, dimeticona, etilhexilo de metoxirileno, neopentil glicol diheptanoato, estearato de glicerilo, butilenglicol, neopentanoato de isodecanoato, succinato-20 acetato PPG-2, metacrilato de polimetilo, acrilamida/copolimero de acrilodimetilsulfato sódico, bakuchiol, palmitato de retinilo, acetato de tocoferilo, bisabolol, hidroxipropilcelulosa, glicolato de sorbitano, retinol, retinoato de hidroxipropilcelulosa, miristil monapéptido-3, palmitoil oligopéptido, palmitoil tetrapéptido-7, tocoferol, ascorbato de sodio, hialuronato de sodio, triglicérido caprílico/caprílico, polímero entrecruzado de dimeticona, polímero entrecruzado de acrilato alquílico acrilatos/C10-30, alcohol behénico, lactato de sodio, etilhexilglicerina, isohexadecano, polisorbato 80, polisorbato 20, isocetido de dimetilo, goma xantánica, carbómero, EDTA disódico, hidróxido de sodio, perilsulfato, clorfenesina, fenotetanol, caprilo glicol, ácido cítrico, sorbato de potasio, fragancia

¿Preguntas?
 Llame sin costo al 1-877-99-GENOM (43666) de lunes a viernes, de 8:00 a. m. a 6:00 p. m., horario central



Cicatricure®
ADVANCED ANTI-WRINKLE THERAPY
 Terapia Avanzada Anti-Arrugas

*Actual size

Cicatricure®

ADVANCED ANTI-WRINKLE THERAPY
 Terapia Avanzada Anti-Arrugas

BROAD SPECTRUM SPF 30
 AMPLIO ESPECTRO FPS 30

With Sunscreen / Con Pantalla Solar

Wrinkle & Age Defying Moisturizer
 [Hidratante para Arrugas y Envejecimiento de la Piel]

- Visibly diminishes the appearance of wrinkles
- Nourishes skin, enhancing firmness & elasticity
- Protects from damaging UV rays
- Disminuye visiblemente arrugas y líneas de expresión
- Nutre la piel, mejorando la firmeza y elasticidad
- Proteje del daño de los rayos UV

Net Wt. 1.5 oz (42g)

ADVANCED ANTI-WRINKLE THERAPY CICATRICURE

avobenzone 3%, octinoxate 7.5%, octisalate 5%, octocrylene 2.7%, oxybenzone 4% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	2.7 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 g in 100 g

Inactive Ingredients

	Ingredient Name	Strength
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
	ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
	PPG-2 ISOCETETH-20 ACETATE (UNII: B16C7YO419)	
	POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
	BAKUCHIOL (UNII: OT12HJU3AR)	
	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
	LEVOMENOL (UNII: 24WE03BX2T)	
	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
	SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
	RETINOL (UNII: G2SH0XKK91)	
	HYDROXYPINACOLONE RETINOATE (UNII: NJ3V2F02E1)	
	MYRISTOYL PENTAPEPTIDE-4 (UNII: PMA59A699X)	
	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
	TOCOPHEROL (UNII: R0ZB2556P8)	
	SODIUM ASCORBATE (UNII: S033EH8359)	
	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
	DOCOSANOL (UNII: 9G10E216XY)	
	SODIUM LACTATE (UNII: TU7HW0W0QT)	
	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
	ISOHEXADECANE (UNII: 918X10UF1E)	
	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
	DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
	XANTHAN GUM (UNII: TTV12P4NEE)	
	POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
	EDETATE DISODIUM (UNII: 7FLD91C86K)	
	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
	CHLORPHENESIN (UNII: I670DAL4SZ)	
	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
	WATER (UNII: 059QF0KO0R)	
	GLYCERIN (UNII: PDC6A3C0OX)	
	DIMETHICONE (UNII: 92RU3N3Y1O)	
	ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
	NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
	GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-121-01	1 in 1 CARTON	01/21/2019	

1	42 g in 1 TUBE; 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	01/21/2019	

Labeler - Genomma Lab (832323534)

Registrant - CGI Packaging, LLC (080691099)

Establishment			
Name	Address	ID/FEI	Business Operations
CGI Packaging, LLC		080691099	manufacture(50066-121)

Revised: 1/2019

Genomma Lab