

SCAR CREAM SPF 30- avobenzene, octocrylene, oxybenzone 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

Avobenzene 3%, Octocrylene 10%, Oxybenzone 6%

Purpose

Sunscreen

Uses

- Helps prevent sunburn

Warnings

For external use only.

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

Do not use on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes 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 generously and evenly 15 minutes before sun exposure. Reapply:

- at least every 2 hours
- use a water resistant sunscreen if swimming or sweating

Children under 6 months: ask a doctor.

Inactive Ingredients

Water, Allium Cepa (Onion) Bulb Extract, Sorbitan Isostearate, Sorbitol, Polyester-7, VP/Eicosene Copolymer, Glyceryl Caprylate, decolorized Aloe Barbadensis Leaf Extract, Chamomilla Recutita Flower Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Lepidium Sativum (Cress) Sprout Extract, Allantoin, Tocopherol, Stearic Acid, Polysorbate 80, Carbomer, Dimethicone, Disodium EDTA, Lecithin, Glycerin, Neopentyl Glycol Diheptanoate, Polyglyceryl-3 Distearate, Benzyl Alcohol, Triethanolamine, Phenoxyethanol

Label

Cicatricure®

NEW

Cicatricure®

SCAR CREAM + SUNSCREEN SPF 30

Crema para Cicatrices + Pantalla Solar FPS 30

FOR SCARS:
To reduce appearance of scars, apply evenly and gently onto scar 3 times daily for 8 weeks.

REDUCES
the appearance of old & new scars

Helps make
scars feel softer & smoother

Visibly reduces the appearance of Scars
Protects from harmful sun exposure

Reduce visiblemente la apariencia de cicatrices
Protege la piel del daño solar



Net Wt. 0.7 oz (19.8 g)



Drug Facts

Active ingredients
Avobenzone 3% Sunscreen
Octocrylene 10% Sunscreen
Oxybenzone 6% Sunscreen

Uses
• helps prevent sunburn

Warnings
For external use only

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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 generously and evenly 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating.
• Children under 6 months of age: ask a doctor

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

Inactive ingredients
Water, Allium Cepa (Onion) Bulb Extract, Sorbitan Isoesterate, Sorbitol, Polyester-7, VPiEicosene Copolymer, Glycerol Caprylate, decolorized Aloe Barbadosensis (Aloe) Leaf Extract, Chamomilla Recutita (Chamomile) Flower Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Lepidium Sativum (Cress) Seed Oil, Allantoin, Tocopherol, Stearic Acid, Polyorbate 80, Carbomer, Dimethicone, Disodium EDTA, Lactin, Glycerin, Neopentyl Glycol Diheptanoate, Polyglyceryl-3 Distearate, Benzyl Alcohol, Triethanolamine, Phenoxethanol

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
www.genommelab.us



Datos del fármaco

Principios activos
Avobenzone 3 % Filtro solar
Octocrieno 10 % Filtro solar
Oxibenzona 6 % Filtro solar

Usos
• ayuda a prevenir las quemaduras solares

Precauciones
Para uso externo únicamente

Alerta de cáncer de piel / Envejecimiento de la piel: Pasar tiempo al sol aumenta el riesgo de cáncer de piel y envejecimiento prematuro de la piel. Este producto se ha mostrado sólo para ayudar a prevenir las quemaduras solares, no cáncer de la piel y el envejecimiento prematuro de la piel.

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. • 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, Extracto de Bulbo de Allium cepa (Cebolla), Extracto de Sorbitano, Sorbitol, Polietileno-7, VPiCopolímero Eicoseno, Caprilato de Glicerilo, Extracto de Hoja de Aloe Barbadosensis (Aloe vera) decolorado, Extracto de Flor de Chamomilla Recutita (Manzanilla), Aceite de Semilla de Simmondsia Chinensis (Jojoba), Extracto de Brote de Lepidium Sativum (Mostaza), Asantón, Tocoférol, Ácido Estearico, Polisorbato 80, Carbómero, Dimeticona, EDTA disódico, Lactina, Glicerina, Neopentil Glicol Dihexanoato, Diésterato de Poliglicérol-3, Alcohol Benzílico, Trietanolamina, Fenoxietanol

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

PARA CICATRICES:
Para disminuir el aspecto de las cicatrices, aplique de manera uniforme y suave sobre una cicatriz tres veces al día durante ocho semanas.

REDUCE
la apariencia de cicatrices nuevas y existentes

Ayuda a que las cicatrices se sientan más suaves y lisas

SCAR CREAM SPF 30

avobenzone, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-019
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
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	6 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
MATRICARIA RECUTITA LEAF (UNII: 6I9LN466F0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

DIMETHICONE 200 (UNII: RGS4T2AS00)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)
WATER (UNII: 059QF0KO0R)
ONION (UNII: 492225Q21H)
SORBITOL (UNII: 506T60A25R)
POLYESTER-7 (UNII: 0841698D2F)
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
ALLANTOIN (UNII: 344S277G0Z)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
STEARIC ACID (UNII: 4ELV7Z65AP)
GARDEN CRESS SPROUT (UNII: PWQ18YNR62)
GLYCERIN (UNII: PDC6A3C0OX)
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
TROLAMINE (UNII: 9O3K93S3TK)
JOJOBA OIL (UNII: 724GKU717M)
BENZYL ALCOHOL (UNII: LKG8494WBH)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-019-01	1 in 1 CARTON	01/07/2019	
1		19.8 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	01/07/2019	

Labeler - Genomma Lab (832323534)

Registrant - CGI Packaging, LLC (080691099)

Establishment			
Name	Address	ID/FEI	Business Operations
CGI Packaging, LLC		080691099	manufacture(50066-019)