

COOLA FULL SPECTRUM 360 SUN SILK DROPS SPF 30- avobenzone, homosalate, octisalate, octocrylene liquid
Gordon Laboratories, Inc.

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.

COOLA Full Spectrum 360 Sun Silk Drops SPF 30

DRUG FACTS

Active ingredients

Avobenzone 2.0%, Homosalate 10.0%

Octisalate 5.0%, Octocrylene 6.0%

Purpose

Sunscreen

Uses

* helps prevent sunburn

* if used as directed with other sun protection measures (see **Directions**), decreases the rise 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 doctor if skin rash occurs

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

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 doctor if skin rash occurs

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

Directions

* **shake well** * **apply liberally** 15 minutes before sun exposure

* **reapply:** * after swimming or sweating * immediately after towel drying * at least every 2 hours

* **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses

* children under 6 months: Ask a doctor

Aloe Barbadosensis Leaf Extract (Organic), Anthemis Nobilis (Chamomile) Flower Oil, Butylene Glycol, Butyloctyl Salicylate, Calcium Gluconate, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Organic Safflower) Seed Oil, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Citrus Aurantium Amara (Bitter Orange) Leaf/Twig Extract, Dicaprylyl Carbonate, Glycerin (Organic), Glyceryl Stearate Se, Jasminum Sambac (Jasmine) Leaf Cell Extract, Nylon-12, Olea Europaea (Organic Olive) Fruit Oil, Plankton Leaf Extract, Propanediol, Schinus Molle Extract, Simmondsia Chinensis (Organic Jojoba) Seed Oil, Sodium Benzoate, Sodium Hyaluronate, Sodium Stearoyl Glutamate,

Theobroma Cacao (Cocoa) Seed Extract, Tocopheryl Acetate, Water (Aqua), Xanthan Gum

Other information

* protect this product from excessive heat and direct sun

Questions or comments? Call 760-940-2125

How to use:

Apply daily to cleansed skin. For best results, dispense several drops as needed into palm of hand and apply evenly across face and neck using upward strokes. Drops are perfect for use alone or blended with your everyday skincare and makeup.

SPF 30

COOLA

70%+ organic

**full spectrum 360°
sun silk drops**

indoor+ outdoor
environmental+ digital
UVA/UVB/IR/ HEV protection

1.0 FL OZ / 30 mL

Perfect for use alone or blended with your everyday skincare and makeup.

Farm to Face

vegan

CRUELTY FREE

GLUTEN FREE

Plant Protection

Antioxidant Enriched

broad spectrum SPF 30

Active Ingredients:
Avobenzone 2.0%, Homosalate 10.0%
Octisalate 5.0%, Octocrylene 6.0%

learn more about
full spectrum + plant-tech
at www.coolasuncare.com

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Gouttes de soie du soleil

Drug Facts / Info-médicament

Active ingredients (w/w) / Ingrédients actifs (p/p)	Purpose / Utilité
Avobenzone 2 % Homosalate 10 % Octisalate 5 % Octocrylene / Octocrylène 6 %	Sunscreen / Écran solaire

Warnings / Mises en garde
For external use only
Pour usage externe seulement

Do not use on broken skin.
Ne pas utiliser sur une peau éraflée.


When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Lorsque vous utilisez ce produit, éviter tout contact avec les yeux. Le cas échéant, bien rincer avec de l'eau.


Stop use and ask a doctor if rash occurs.
Cessez d'utiliser et consultez un médecin si une éruption cutanée se développe.


Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.
Garder hors de la portée des enfants. En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.


Directions / Mode d'emploi
Adults and children over 6 months of age: • 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.



Peel for continued Drug Facts / Peler pour la suite de l'information sur le médicament


Farm to Face®


Plant Protection®


Cruelty Free
Sans Cruauté Envers
Les Animaux


Vegan
Végétalien




 Environmental 360°
Sun Silk Drops
 Skin Serum
 Environnement 360°
Gouttes de soie du soleil
 Sérum Cutané
 UVA/UVB Protection
 Broad Spectrum SPF 30
 Protection UVA/UVB
 FPS 30 à large spectre
 DIN 02490854
 1.0 FL. OZ / 30 mL

How to use:
Apply daily to cleansed skin. For best results, dispense several drops into palm of hand and apply evenly for each section of the face and neck, using upward strokes. Drops can be used alongside your everyday makeup and skincare.

Comment utiliser:
Appliquer quotidiennement sur une peau nettoyée. Pour de meilleurs résultats, appliquez plusieurs gouttes dans la paume de la main et appliquez uniformément sur chaque section du visage et du cou, en effectuant des mouvements ascendants. Les gouttes peuvent être utilisées aux côtés de votre maquillage et de votre soin de la peau au quotidien.

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non-comedogenic / non comédogène



Made in USA with thoughtfully sourced global ingredients
Fabriqué aux États-Unis avec des ingrédients rigoureusement sélectionnés dans le monde entier

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COOLA FULL SPECTRUM 360 SUN SILK DROPS SPF 30

avobenzone,homosalate, octisalate,octocrylene liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:218 39-620
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PROPANEDIOL (UNII: 5965N8W85T)
OLIVE OIL (UNII: 6UYK2W1W1E)
GLUCONOLACTONE (UNII: WQ29KQ9POT)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
COCOA (UNII: D9108TZ9KG)
SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)
JASMINUM SAMBAC FLOWER (UNII: 2S686I937F)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)
SAFFLOWER OIL (UNII: 65UEH262IS)
NYLON-12 (UNII: 446U8J075B)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)
XANTHAN GUM (UNII: TTV12P4NEE)
JOJOBA OIL (UNII: 724GKU717M)
GLYCERIN (UNII: PDC6A3C0OX)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21839-620-02	1 in 1 NOT APPLICABLE	12/20/2018	
1	NDC:21839-620-01	5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21839-620-04	1 in 1 CARTON	12/20/2018	
2	NDC:21839-620-03	30 mL 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 final	part352	12/20/2018	

Labeler - Gordon Laboratories, Inc. (008328619)

Registrant - Gordon Laboratories, Inc. (008328619)

Establishment

Name	Address	ID/FEI	Business Operations
GORDON LABORATORIES, INC		008328619	manufacture(21839-620)