

**LEADER GENERAL PROTECTION SPF 30 SUNSCREEN- avobenzone,  
homosalate, octisalate, octocrylene lotion  
CARDINAL HEALTH, 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.*

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**Leader General Protection SPF 30 Sunscreen Lotion**

***Active ingredients***

Avobenzone 3.0%  
Homosalate 10.0%  
Octisalate 5.0%  
Octocrylene 10.0%

***Purpose***

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
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- 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 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

## ***Other information***

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

## ***Inactive ingredients***


water, sorbitol, ethylhexyl palmitate, polyamide-8, benzyl alcohol, diethylhexyl syringylidenemalonate, tocopherol (vitamin E), caprylic/capric triglyceride, triethanolamine, fragrance, acrylates/C10-30 alkyl acrylate crosspolymer, chlorphenesin, sodium ascorbyl phosphate, retinyl palmitate, oleth-3, disodium EDTA



### General Protection Sunscreen Moisturizing Lotion

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3.0% Homosalate 10.0% Octisalate 5.0% Octocrylene 10.0%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• helps prevent sunburn</li> <li>• if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• apply liberally 15 minutes before sun exposure</li> <li>• reapply:               <ul style="list-style-type: none"> <li>• after 80 minutes of swimming or sweating</li> <li>• immediately after towel drying</li> <li>• at least every 2 hours</li> </ul> </li> <li>• children under 6 months of age: Ask a doctor</li> <li>• <b>Sun Protection Measures.</b> 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:               <ul style="list-style-type: none"> <li>• limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>• wear long-sleeved shirts, pants, hats, and sunglasses</li> </ul> </li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• protect the product in this container from excessive heat and direct sun</li> <li>• may stain or damage some fabrics, materials or surfaces</li> </ul>	
<b>Inactive ingredients</b>	
water, sorbitol, ethylhexyl salicylate, polyamide-6, benzyl alcohol, diethylhexyl syringyl dimethylmaleate, tocopherol (vitamin E), caprylic/capric triglyceride, triethanolamine, fragrance, acrylates/C10-30 alkyl acrylate copolymer, chlorphenesin, sodium ascorbyl phosphate, retinyl palmitate, cetyl-3, disodium EDTA	
<b>Questions or comments?</b>	
Call toll free 1-800-527-7731	

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†Formula is compliant with H 5825/1




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## LEADER GENERAL PROTECTION SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0536
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TROLAMINE</b> (UNII: 903K93S3TK)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>POLYAMIDE-8 (4500 MW)</b> (UNII: 77723GV81A)	
<b>DIETHYLHEXYL SYRINGYLIDENEMALONATE</b> (UNII: 3V5U97P248)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CARBOMER COPOLYMER TYPE A</b> (UNII: 71DD5V995L)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>OLETH-3</b> (UNII: BQZ26235UC)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0536-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/19/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/19/2019	

**Labeler** - CARDINAL HEALTH, INC. (063997360)

Revised: 11/2022

CARDINAL HEALTH, INC.