

**CARDINAL HEALTH LEADER GENERAL PROTECTION SUNSCREEN SPF 50-  
avobenzene, homosalate, octisalate, octocrylene lotion  
CARDINAL HEALTH, INC.**

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**Cardinal Health Leader General Protection Sunscreen SPF 50 Lotion**

**Active ingredients**

Avobenzene 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 7.0%

**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 and evenly 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, tridecyl salicylate, sorbitol, stearic acid, aluminum starch octenylsuccinate, triethanolamine, polyethyloxazoline, carbomer, dimethicone, tocopherol, disodium EDTA, polyglyceryl-3 distearate, caprylyl glycol, phenoxyethanol, ethylhexylglycerin, sorbitan isostearate, benzyl alcohol, fragrance

### **Label**

Cardinal Health Leader General Protection Sunscreen SPF 50 Lotion

8 fl oz (237 mL)

NDC 70000-0075-1

**LEADER?**<sup>TM</sup>

NDC 70000-0075-1

**General Protection  
Sunscreen**  
Moisturizing Lotion

**50**

Broad Spectrum  
SPF 50

Reef-Conscious  
Formula†

Water Resistant  
(80 Minutes)

Octinoxate,  
Oxybenzone  
& Paraben-Free\*\*

UVA/UVB  
Protection

COMPARE TO  
COPPERTONE®  
ULTRA GUARD®  
SPF 50  
active ingredients\*

100% Money  
Back Guarantee

**8 FL OZ (237 mL)**

**General Protection Sunscreen  
Moisturizing Lotion**

<b>Drug Facts</b>		
<b>Active Ingredients</b>	<b>Purpose</b>	
Avobenzone 3.0% Homosalate 15.0% Octisalate 5.0% Octocrylene 7.0%	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 <b>Directions</b>), 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 and evenly 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>		
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<b>Inactive ingredients</b>		
water, triethyl salicylate, sorbitol, stearic acid, aluminum starch octenylsuccinate, triethanolamine, polyethyloxazoline, carbomer, dimethicone, tocopherol, disodium EDTA, polyglyceryl-3 distearate, caprylyl glycol, phenoxyethanol, ethylhexylglycerin, sorbitan isostearate, benzyl alcohol, fragrance		
<b>Questions or comments?</b>		
Call toll free 1-800-527-7731		

\*This product is not manufactured or distributed by Beiersdorf AG, owner of the registered trademark Coppertone® Ultra Guard®.

\*\*No parabens separately added to preserve this product

†Formula is compliant with HI SB2571.



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CIN 5683222 REV. 12/20



**CARDINAL HEALTH LEADER GENERAL PROTECTION SUNSCREEN SPF 50**

avobenzone, homosalate, octisalate, octocrylene lotion

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:70000-0075

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>POLYETHYLOXAZOLINE (5000 MW)</b> (UNII: HNX7574GTX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ006294)	
<b>POLYGLYCERYL-3 DISTEARATE</b> (UNII: ZI1LK470XV)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0075-1	237 g in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/10/2020	

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