CARDINAL HEALTH LEADER GENERAL PROTECTION SUNSCREEN SPF 50- 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.

Cardinal Health Leader General Protection Sunscreen SPF 50 Lotion

Active ingredients

Avobenzone 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

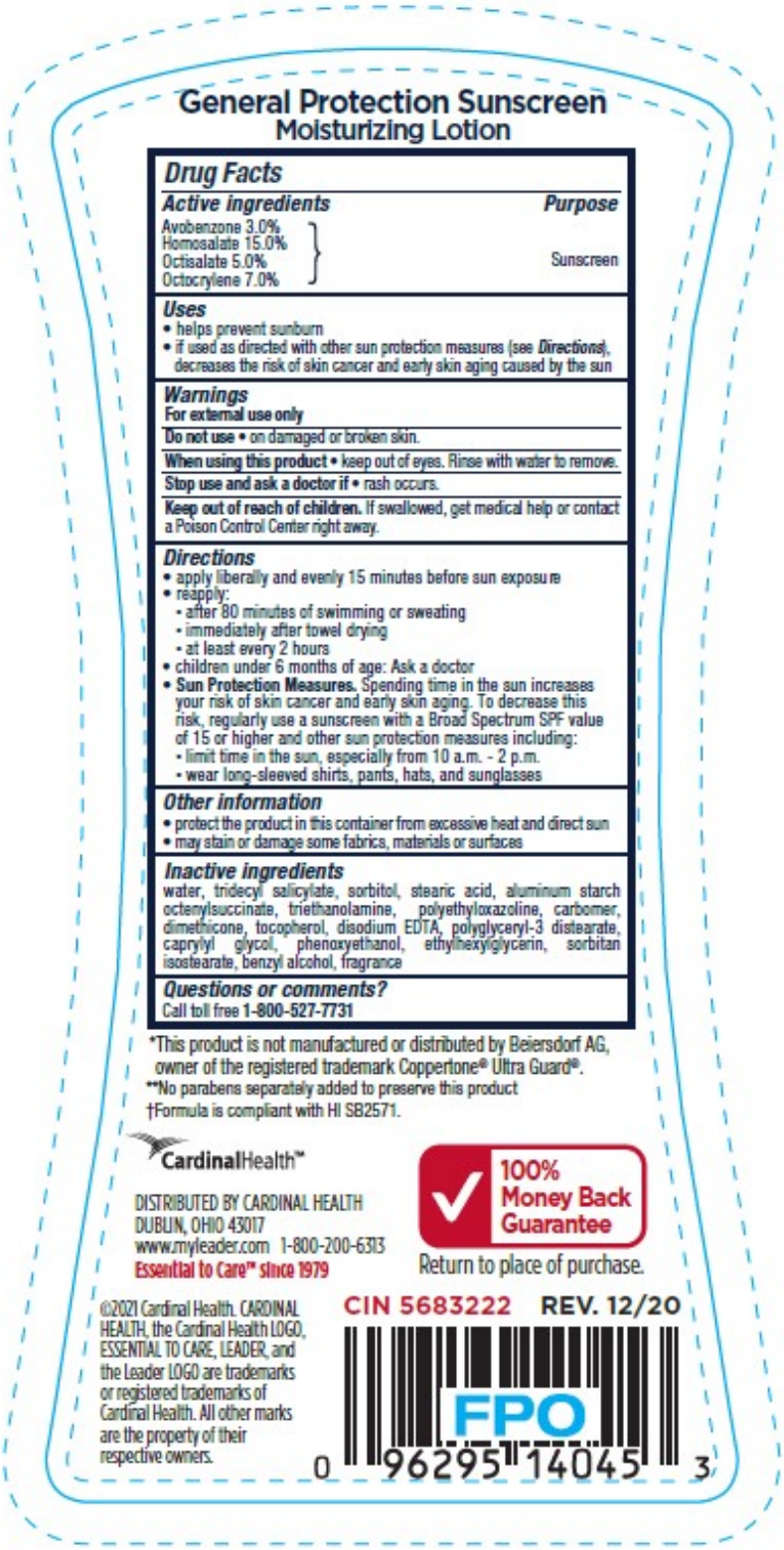
Label

Cardinal Health Leader General Protection Sunscreen SPF 50 Lotion

8 fl oz (237 mL)

NDC 70000-0075-1


LEADER™
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)



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
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SORBITOL (UNII: 506T60A25R)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYETHYLOXAZOLINE (5000 MW) (UNII: HNX7574GTX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBITAN ISOSTEARATE (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 not final	part352	12/10/2020	

Labeler - CARDINAL HEALTH, INC. (063997360)