

**LEADER SPORT SUNSCREEN SPF 50 MOISTURIZING- 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.

Leader Sport Sunscreen SPF 50 Moisturizing Lotion

Active ingredients

Avobenzone 3.0%
Homosalate 10.0%
Octisalate 4.5%
Octocrylene 8.0%

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, Polyester-7, Neopentyl Glycol Diheptanoate, Glycerin, Aluminum Starch Octenylsuccinate, Styrene/Acrylates Copolymer, Silica, Phenoxyethanol, Isododecane, Arachidyl Alcohol, Beeswax, Ethylhexylglycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Behenyl Alcohol, Tocopherol (Vitamin E), Arachidyl Glucoside, Glyceryl Stearate, PEG-100 Stearate, Potassium Hydroxide, Disodium EDTA, Sodium Ascorbyl Phosphate, Fragrance.

Label



**Sport Sunscreen
Moisturizing Lotion**

Drug Facts	
Active ingredients	Purpose
Avobenzone 3.0% Homosalate 10.0% Octisalate 4.5% Octocrylene 8.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure reapply: <ul style="list-style-type: none"> 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 of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. - 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses 	
Other information	
<ul style="list-style-type: none"> protect this product from excessive heat and direct sun may stain or damage some fabrics, materials or surfaces 	
Inactive ingredients	
Water, Polyester-7, Nonyl Glycol Diheptanoate, Glycerin, Aluminum Starch Octylsuccinate, Styrene/Acrylates Copolymer, Silica, Phenoxyethanol, Isododecane, Arachidyl Alcohol, Beeswax, Ethylhexylglycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Behenyl Alcohol, Tocopherol (Vitamin E), Arachidyl Glucoside, Glyceryl Stearate, PEG-100 Stearate, Potassium Hydroxide, Disodium EDTA, Sodium Ascorbyl Phosphate, Fragrance.	
Questions or comments?	
Call toll free 1-800-527-7731	

*This product is not manufactured or distributed by Beiersdorf AG, owner of the registered trademark Coppertone® brand products. Formula is compliant with § 302.57

©2021 Cardinal Health, CARDINAL HEALTH, the Cardinal Health LOGO, ESSENTIAL TO CARE, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myLeader.com
1-800-200-6513

Essential to Care™ since 1979

100% Money Back Guarantee
Return to place of purchase if not satisfied.

CIN 5318118 REV. 12/20

LEADER SPORT SUNSCREEN SPF 50 MOISTURIZING

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0257
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 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35J00J)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISODODECANE (UNII: A8289P68Y2)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
DOCOSANOL (UNII: 9G1OE216XY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
WATER (UNII: 059QF0KO0R)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0257-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/22/2019	

Labeler - CARDINAL HEALTH, INC. (063997360)