LEADER ULTRA SHEER SPF 100 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone 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 Ultra Sheer SPF 100 Sunscreen Lotion

Active ingredients

Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 10.0%, Oxybenzone 6.0%

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

Inactive ingredients

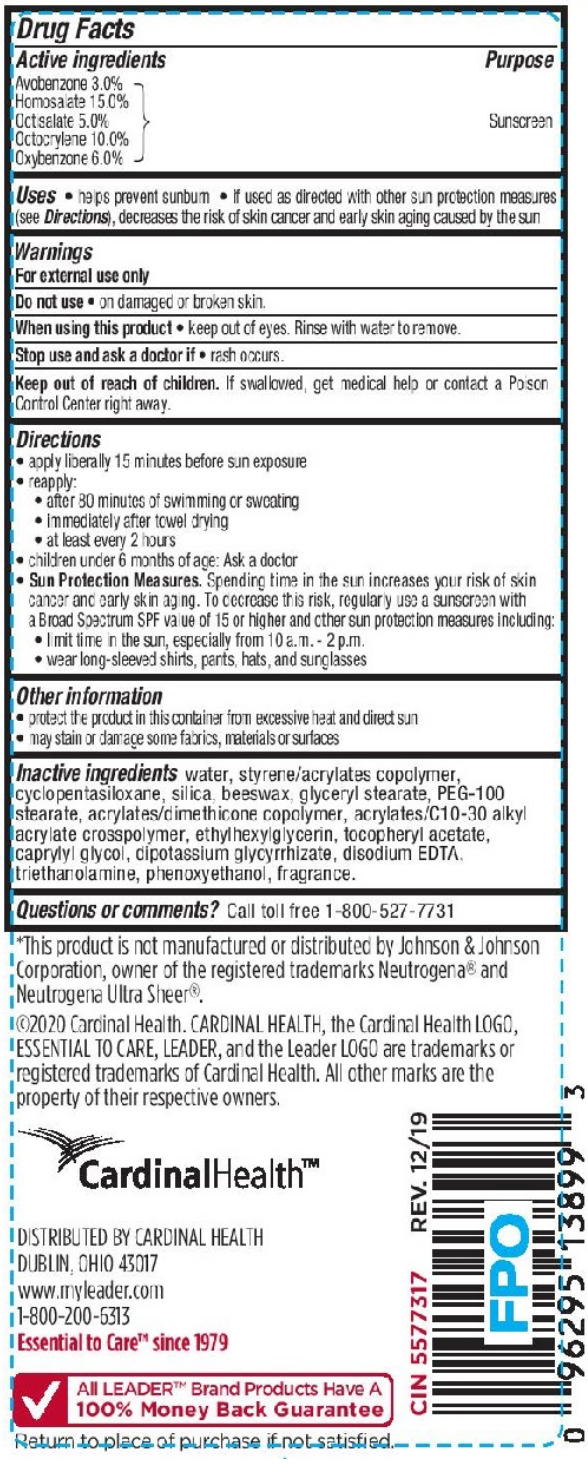
water, styrene/acylates copolymer, cyclopentasiloxane, silica, beeswax, glyceryl stearate, PEG-100 stearate, acrylates/dimethicone copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, ethylhexylglycerin, tocopheryl, caprylyl glycol, dipotassium glycyrrhizate, disodium EDTA, triethanolamine, phenoxyethanol, fragrance.

Label

Leader Ultra Sheer SPF 100 Sunscreen Lotion

3 FL OZ (89 mL)

NDC 70000-0535-1



Drug Facts

Active ingredients — **Purpose**

Avobenzone 3.0%
Homosalate 15.0%
Octisalate 5.0%
Octocrylene 10.0%
Oxybenzone 6.0% — 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, styrene/acrylates copolymer, cyclopentasiloxane, silica, beeswax, glyceryl stearate, PEG-100 stearate, acrylates/dimethicone copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, ethylhexylglycerin, tocopheryl acetate, caprylyl glycol, dipotassium glycyrrhizate, disodium EDTA, triethanolamine, phenoxyethanol, fragrance.

Questions or comments? Call toll free 1-800-527-7731

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademarks Neutrogena® and Neutrogena Ultra Sheer®.

CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com
1-800-200-5313
Essential to Care™ since 1979

All LEADER™ Brand Products Have A 100% Money Back Guarantee
Return to place of purchase if not satisfied.

REV. 12/19
CIN 5577317
FPO
0 96295 13899 3

LEADER ULTRA SHEER SPF 100 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0535
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	150 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WHITE WAX (UNII: 7G1J5DA97F)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0535-1	89 mL in 1 TUBE; Type 0: Not a Combination Product	12/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/03/2019	

Labeler - CARDINAL HEALTH, INC. (063997360)

Revised: 6/2021 CARDINAL HEALTH, INC.