

**LEADER GENERAL PROTECTION SUNSCREEN SPF 30- avobenzene, homosalate, octisalate, octocrylene, oxybenzone lotion**  
**Cardinal Health**

*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 Sunscreen Moisturizing Lotion SPF 30**

**Active Ingredients**

Avobenzene 2.0%, Homosalate 10.5%, Octisalate 5.0%, Octocrylene 2.0%, Oxybenzone 2.0%

**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 doctor if rash occurs.

**Keep out of reach of children.**

If product is 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

- **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:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: ask a doctor

### **Inactive Ingredients**

water, sorbitan isostearate, sorbitol, triethanolamine, polyglyceryl-3 distearate, stearic acid, octadecene/MA copolymer, barium sulfate, benzyl alcohol, VP/eicosene copolymer, dimethicone, carbomer, methylparaben, aloe barbadensis leaf extract, simmondsia chinensis (jojoba) seed oil, tocopherol (vitamin E), cocos nucifera (coconut) oil, mineral oil, propylparaben, fragrance, disodium EDTA

### **Other information**

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

Leader General Protection Sunscreen Moisturizing Lotion SPF 30

Product NDC 37205-728



## LEADER GENERAL PROTECTION SUNSCREEN SPF 30

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-728
<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	20 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	105 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	20 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>MALEIC ACID</b> (UNII: 91XW058U2C)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>POLYGLYCERYL-3 DISTEARATE</b> (UNII: Z11LK470XV)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>OCTADECENE</b> (UNII: H5ZUQ6V4AK)	
<b>BARIUM SULFATE</b> (UNII: 25BB7EKE2E)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>COCOS NUCIFERA WHOLE</b> (UNII: 245J88W96L)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-728-34	237 mL in 1 CAN; Type 0: Not a Combination Product	01/15/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/15/2012	

**Labeler** - Cardinal Health (097537435)