WALGREENS SUNSCREEN BROAD SPECTRUM SPF 30- avobenzone homosalate octisalate octocrylene lotion WALGREEN CO.

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.

Drug Facts

Active Ingredients

Avobenzone 3.0 %

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 10.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions) decrease 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 product is swallowed get medical help or contact a Poison Control Center right away.

• May stain some fabrics.

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 increase 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 am 2 pm
- Wear long sleeves shirts, pants, hats and sunglasses
- children under 6 month of age: Ask a doctor

Inactive Ingredients

Water, Ethylhexyl Palmitate, Sorbitol, Polyglyceryl-3 Methylglucose Distearate, Diethylhexyl Syringylidenemalonate, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Glyceryl Stearate, PEG-100 Stearate, Caprylic/Capric Triglyceride, Disodium EDTA, Oleth-3, Tocopherol, Aloe Barbadensis Leaf Juice Powder, Sodium Ascorbyl Phosphate, Benzyl Alcohol, Chlorphenesin, Fragrance.

Other information

Protect this product from excessive heat and direct sun.

Questions or comments

1-800-WALGREENS (1-800-925-4733)

Principal Display Panel

NDC 0363-4016-29

VALUE SIZE

Well at

Walgreens

LOTION

Sunscreen

Broad Spectrum SPF 30

- Water resistant (80 minutes)
- UVA/UVB protection

16 FL OZ (473 mL)





NDC 0363-4016-22

Well at Walgreens

WALGREENS PHARMACIST RECOMMENDED

SUNSCREEN

Lotion

Broad Spectrum SPF 30

- Water resistant (80 minutes)
- UVA/UVB protection

30

10 FL OZ (296 mL)



NDC 0363-4016-19
Well at Walgreens
WALGREENS PHARMACIST RECOMMENDED
SUNSCREEN
Lotion

Broad Spectrum SPF 30

- Water resistant (80 minutes)
- UVA/UVB protection

30

3 FL OZ (88 mL)



avobenzone homosalate octisalate octocrylene lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4016	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SORBITOL (UNII: 506T60A25R)	
DIETHYLHEXYL SYRINGYLIDENEMALO NATE (UNII: 3V5U97P248)	
TROLAMINE (UNII: 903K93S3TK)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
OLETH-3 (UNII: BQZ26235UC)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4016- 29	465 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/07/2013	
2	NDC:0363-4016- 22	296 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/09/2016	
3	NDC:0363-4016- 19	88 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/09/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/07/2013	

Labeler - WALGREEN CO. (008965063)

Establishment				
Name	Address	ID/FEI	Business Operations	
Playtex Manufacturing Co.		963501502	manufacture(0363-4016)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Schick Manufacturing Inc.		193866378	relabel(0363-4016)	

Revised: 6/2016 WALGREEN CO.