

FIRST AID ONLY SUNX30 SUNSCREEN- avobenzene, homosalate, octisalate, octocrylene lotion

Acme United Corporation

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.

First Aid Only SunX30 Sunscreen Lotion

Active ingredients

Avobenzene 3%

Homosalate 7.5%

Octisalate 5%

Octocrylene 5%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Warnings

For external use only

Do not use

on damaged or broken skin

When using this product

keep out of the eyes. Rinse with water to remove

Stop use and ask a doctor

if rash occurs

Keep out of the reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

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.

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 10:00 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses.

Children under 6 months: Ask a doctor

Other information

- Protect this product from excessive heat or direct sun.

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, C12-15 alkyl benzoate, carbomer, disodium EDTA, ethylhexylglycerin, hydroxypropyl methylcellulose, phenoxyethanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan, oleate, theobroma cacao (cocoa) seed butter, tocopherol acetate, water

Questions

1-800-835-2263

carton image

18-030
MISC

SunX30® Sunscreen

18-030
MISC



18-030
MISC

Drug Facts	Drug Facts (continued)
<p>Active Ingredients</p> <p>Avobenzone 3% Sunscreen Homosalate 7.5% Sunscreen Octisalate 5.0% Sunscreen Octocrylene 5.0% Sunscreen</p> <p>Uses</p> <p>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.</p> <p>Warnings</p> <p>For external use only.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If swallowed get medical help or contact a poison control center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure. reapply at least every 2 hours. reapply after 80 minutes of swimming or sweating. 	<p>reapply immediately after towel drying.</p> <p>■ 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:</p> <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. - 2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses. <p>Children under 6 months of age: Ask a doctor.</p> <p>Inactive ingredients</p> <p>acrylates/c10-30 alkyl acrylate crosspolymer, aloe barbadensis leaf juice, c12-15 alkyl benzoate, carbomer, disodium EDTA, ethylhexylglycerin, hydroxypropyl methylcellulose, phenylethanol, polyethylene, polysorbate 20, propylene glycol, sodium hydroxide, sorbitan oleate, theobroma cacao (cocoa) seed butter, tocopheryl acetate, water</p> <p>Other information</p> <p>Protect this product from excessive heat and direct sun.</p> <p>Questions</p> <p>1.800.835.2263</p>

SunX30® Sunscreen

SunX30® Sunscreen
 4 Packets of Water Resistant
 Sunscreen Lotion – 0.25 OZ each



SunX30® Sunscreen

SunX30® is a registered trademark of CoreTex Products, Inc.

Manufactured for:
Acme United Corporation
 55 Walls Dr, Fairfield, CT 06824
 www.FirstAidOnly.com
 Made in the USA
 © 2021 Acme United Corporation.



807622-revA

FIRST AID ONLY SUNX30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-0801(NDC:65753-106)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PEG-6 SORBITAN OLEATE (UNII: 58O7V09UCI)	
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
PROPYLENE GLYCOL PROPYL ETHER (UNII: 92KA3PYX0S)	
MEDIUM DENSITY POLYETHYLENE (UNII: 3W404QE89S)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0801-01	4 in 1 CARTON	02/22/2021	
1		7 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/22/2021	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-0801) , repack(0924-0801)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0801) , repack(0924-0801)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		117825595	relabel(0924-0801) , repack(0924-0801)

Revised: 2/2021

Acme United Corporation