

CORTEX SUNX 50 THICK- avobenzone, homosalate, octisalate, octocrylene lotion
CoreTex Products

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.

CoreTex SunX 50 Thick

Active ingredients

Avobenzone 2.4%

Homosalate 12%

Octisalate 4%

Octocrylene 4.8%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other 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 (or generously) and evenly 15 minutes before sun exposure.

Sun Protection Measures: spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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 am to 2 pm
- wear long-sleeved shirt, pants, hat and sunglasses

reapply

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every two hours

Children under 6 months of age: Ask a doctor.

Other information

- protect this product from excessive heat and direct sun.

Inactive ingredients

benzoic acid, caprylyl methicone, cetyl PEG/PPG-10/1 dimethicone, dicaprylyl ether, disodium EDTA, ethylhexylglycerin, glycereth-2 cocoate, octyldodecyl stearyl citrate crosspolymer, phenoxyethanol, propylene glycol, sodium chloride, water.

Questions?

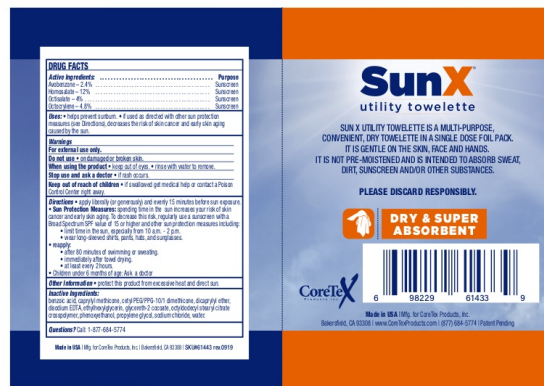
Call: 1-877-684-5774

Principal Display Panel

Front



Back



CORTEX SUNX 50 THICK

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65753-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	12 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4.8 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MYRISTYL TRISILOXANE (UNII: J7960S4R1T)	
OCTYLDODECYL STEARATE (UNII: K6F16QGO28)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-601-22	25 in 1 CONTAINER	11/22/2019	
1		7 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:65753-601-23	25 in 1 CONTAINER	11/22/2019	
2		7 mL in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:65753-601-24	50 in 1 CONTAINER	11/22/2019	
3		7 mL in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:65753-601-26	150 in 1 CARTON	11/22/2019	
4		7 mL in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:65753-601-31	300 in 1 CARTON	11/22/2019	
5		7 mL in 1 POUCH; 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	11/22/2019	

Labeler - CoreTex Products (061944620)

Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products		061944620	label(65753-601)

Establishment

Name	Address	ID/FEI	Business Operations
Helath Specialty		794053863	manufacture(65753-601)