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

CoreTex SunX 50 Thick Multipack 65753-602

Active Ingredients:

Avobenzone...3%

Homosalate...10%

Octisalate...5%

Octocrylene...5%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Uses:

- helps prevent sunburn.
- higher SPF gives more sunburn protection.
- retains SPF after 80 minutes of activity in the water or sweating.
- provides high protection against sunburn.

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 or irritation develops and lasts

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
- after towel drying, swimming, or
- at least every 2 hours
- Children under 6 months of age: ask a doctor.

Other Information:

• Protect this product from excessive heat and direct sun.

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbedensis 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, tocopheryl acetate, water.

Questions?

Call: 1-877-684-5774

65753-602-24



65753-602-22,-23,-26,and -31



Front



Back

CORTEX SUNX 50 THICK

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65753-602	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g	

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0KO0R)	
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-6 SORBITAN OLEATE (UNII: 5807V09UCI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
MEDIUM DENSITY POLYETHYLENE (UNII: 3W404QE89S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-602- 22	25 in 1 CONTAINER	03/09/2023	
1		7 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:65753-602- 23	25 in 1 CONTAINER	03/09/2023	
2		7 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:65753-602- 24	50 in 1 CONTAINER	03/09/2023	
3		7 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:65753-602- 26	150 in 1 CARTON	03/09/2023	
4		7 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:65753-602- 31	300 in 1 CARTON	03/09/2023	
5		7 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/09/2023	

Labeler - CoreTex Products Inc (061944620)

Establishment				
Name	Address	ID/FEI	Business Operations	
CoreTex Products Inc		061944620	pack(65753-602)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Prime Enterprises		101946028	manufacture(65753-602)	

Revised: 10/2023 CoreTex Products Inc