CORETEX SUN X SPF 30- avobenzone, homosalate, octinoxate, octisalate, oxybenzone 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.

Sun X SPF 30 Thick

Active ingredients

Avobenzone 1.0%

Homosalate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 6.0%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

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 the eyes
- rinse with water to remove

Stop use and ask a doctor if

- rash occurs

Keep out of the reach of children

If swallowed get medical help or contact a Poison Control center right away.

Directions

- apply liberally 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 this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and after 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.
- reapply:
- - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- children under 6 months of age: 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, butylparaben, calendula officinalis flower extract, carbomer, chamomile recutita extract, dimethicone, dimethyl capramide, ethylparaben, fragrance, glyceryl stearate, isobutylparaben, methylparaben, nasturtium officinale extract, peg-100 stearate, phenoxyethanol, propylparaben, symphytum officinale leaf extract, tetrasodium EDTA, triethanolamine, tocopherol, tocopherol acetate, water

Questions?

Call 1-877-684-5774

Principal Display Panel

image of pdp

CORETEX SUN X SPF 30

avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65753-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	
CHAMOMILE (UNII: FGL3685T2X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	
NASTURTIUM OFFICINALE (UNII: YH89GMV676)	
COMFREY LEAF (UNII: DG4F8T839X)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Product Characteristics			
Color	white (Thick White Lotion)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-100-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/26/2019	
2	NDC:65753-100-32	44 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
3	NDC:65753-100-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
4	NDC:65753-100-33	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
5	NDC:65753-100-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
6	NDC:65753-100-34	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
7	NDC:65753-100-04	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
8	NDC:65753-100-05	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
9	NDC:65753-100-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
10	NDC:65753-100-09	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
11	NDC:65753-100-10	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2013	
12	NDC:65753-100-37	44 mL in 1 PACKET; Type 0: Not a Combination Product	01/25/2013	
13	NDC:65753-100-18	1000 in 1 CARTON	01/25/2013	
13		44 mL in 1 PACKET; Type 0: Not a Combination Product		
14	NDC:65753-100-22	25 in 1 CONTAINER	01/25/2013	
14		207 mL in 1 PACKET; Type 0: Not a Combination Product		
15	NDC:65753-100-23	50 in 1 CONTAINER	01/25/2013	
15		207 mL in 1 PACKET; Type 0: Not a Combination Product		
16	NDC:65753-100-24	50 in 1 CARTON	01/25/2013	
16		207 mL in 1 PACKET; Type 0: Not a Combination Product		
17	NDC:65753-100-25	100 in 1 CARTON	01/25/2013	
17		207 mL in 1 PACKET; Type 0: Not a Combination Product		
18	NDC:65753-100-26	300 in 1 BOX	01/25/2013	
18		207 mL in 1 PACKET; Type 0: Not a Combination Product		
19	NDC:65753-100-08	1 in 1 BOX	01/25/2013	
19		500 mL in 1 BAG; Type 0: Not a Combination Product		
20	NDC:65753-100-40	1 in 1 BOX	01/01/2017	
20	NDC:65753-100-35	751 mL in 1 BOTTLE; 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	01/25/2013	

Labeler - CoreTex Products (061944620)

Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products		061944620	label(65753-100)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		080354456	manufacture(65753-100)

Revised: 11/2019 CoreTex Products