CORETEX SUN X 50- 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.

Sun X50

Active ingredients

Avobenzone

Homosalate

Octisalate

Octocrylene

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 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 the product from excessive heat and direct sun

Inactive ingredients

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

Questions?

Call 1-877-684-5774

Principal Display Panel

CORETEX SUN X 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65753-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
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
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

Inactive Ingredients	
Ingredient Name	**Strength**
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
WATER (UNII: 059QF0KO0R)	
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)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65753-600-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
2	NDC:65753-600-32	44 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
3	NDC:65753-600-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
4	NDC:65753-600-	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	08/16/2019	

4	33	Product	08/16/2019	
5	NDC:65753-600-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
6	NDC:65753-600-34	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
7	NDC:65753-600-04	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
8	NDC:65753-600-05	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
9	NDC:65753-600-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
10	NDC:65753-600-08	473 mL in 1 BAG; Type 0: Not a Combination Product	08/16/2019	
11	NDC:65753-600-09	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
12	NDC:65753-600-10	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/16/2019	
13	NDC:65753-600-39	7 mL in 1 POUCH; Type 0: Not a Combination Product	08/16/2019	
14	NDC:65753-600-22	175 in 1 CONTAINER	08/16/2019	
14	NDC:65753-600-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
15	NDC:65753-600-23	350 in 1 CONTAINER	08/16/2019	
15	NDC:65753-600-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
16	NDC:65753-600-24	350 in 1 CONTAINER	08/16/2019	
16	NDC:65753-600-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
17	NDC:65753-600-25	700 in 1 CONTAINER	08/16/2019	
17	NDC:65753-600-39	7 mL in 1 POUCH; Type 0: Not a Combination Product		
18	NDC:65753-600-26	2100 in 1 CARTON	08/16/2019	
18	NDC:65753-600-39	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	08/16/2019	

Labeler - CoreTex Products (061944620)

Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products		061944620	label(65753-600)

Establishment

Name	Address	ID/FEI	Business Operations

Health Specialty		794053863	manufacture(65753-600)