

SUN X MULTI-PACK SPF 30 THICK- avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion

CoreTex Products Inc

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.

Cortex Sun X Multi-Pack SPF 30 Thick

ACTIVE INGREDIENTS

Avobenzone 1.0%

Homosalate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 6.0%

PURPOSE

Sunscreen

Sunscreen

Sunscreen

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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 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

Kit Contents

1 Towelette

PRINCIPAL DISPLAY PANEL



SUN X MULTI-PACK SPF 30 THICK

avobenzone, homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65753-102 |
| 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 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 5 g in 100 g |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 g in 100 g |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 5 g in 100 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 6 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| METHYL PARABEN (UNII: A218C7H9T) | |
| C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |

| |
|---|
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| ETHYL PARABEN (UNII: 14255EXE39) |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) |
| TROLAMINE (UNII: 9O3K93S3TK) |
| PEG-100 STEARATE (UNII: YD01N1999R) |
| CARBOMER HOMO POLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC) |
| WATER (UNII: 059QF0KO0R) |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) |
| BUTYL PARABEN (UNII: 3QP1U3FV8) |
| DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ) |
| GLYCERYL MONO STEARATE (UNII: 230OU9XXE4) |
| ISOBUTYL PARABEN (UNII: 0QQJ25X58G) |
| NASTURTIUM OFFICINALE (UNII: YH89GMV676) |
| COMFREY LEAF (UNII: DG4F8T839X) |
| CHAMOMILE (UNII: FGL3685T2X) |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:65753-102-22 | 25 in 1 CONTAINER | 01/01/2017 | |
| 1 | | 7 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 2 | NDC:65753-102-23 | 25 in 1 CONTAINER | 01/01/2017 | |
| 2 | | 7 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 3 | NDC:65753-102-24 | 50 in 1 CONTAINER | 01/01/2017 | |
| 3 | | 7 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 4 | NDC:65753-102-31 | 150 in 1 BOX | 01/01/2017 | |
| 4 | | 7 g in 1 POUCH; Type 0: Not a Combination Product | | |
| 5 | NDC:65753-102-26 | 300 in 1 BOX | 01/01/2017 | |
| 5 | | 7 g 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 | 01/01/2017 | |

Labeler - CoreTex Products Inc (061944620)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| CoreTex Products Inc | | 061944620 | label(65753-102) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Pure Source | | 080354456 | manufacture(65753-102) |

Revised: 1/2020

CoreTex Products Inc