CORETEX ANTI-ITCH GEL- camphor, diphenhydramine, zinc acetate gel
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 Anti-Itch Gel

Active Ingredients

Camphor 0.1%

Diphenhydramine hydrochloride 2%

Zinc acetate 1%

Purpose

Extrenal analgesic

Antihistamine

Skin protectant

Uses

- For the temporary relief of itching and pain associated with minor skin irritations and rashes due to insect bites, poison ivy, poison oak, poison sumac.
- dries the oozing and weeping of poison ivy, poison oak, poison sumac.

Warnings

For external use only

Do Not Use

- on chicken pox, blisters or on extensive areas of the skin
- with any drugs containing diphenhydramine while using this product.

When using this product

- keep out of eyes.

Stop use and ask a doctor if

- conditions worsen or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children

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

Directions

- Adults and children 12 years of age and older, apply to affected area not more than 3 to 4 times daily, or as directed bu a doctor.

Other Information

- protect this product from excessive heat and direct sun.

Inactive Ingredients

citric acid, diazolidinyl urea, glycerin, hydroxypropyl methylcellulose, methylparaben, propylene glycol, propylparaben, SD alcohol 40, sodium citrate, water (aqua).

Questions?

Call: 1-877-684-5774

PRINCIPAL DISPLAY PANEL

CORETEX ANTI-ITCH GEL

camphor, diphenhydramine, zinc acetate gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65753-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.1 g in 100 mL
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC ACETATE	1 g in 100 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL 1-ALLYL ETHER (UNII: QRB8092KPK)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLCELLULOSE (1500 CPS) (UNII: P0NTE48364)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65753-400-04	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2019	
2	NDC:65753-400-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2019	
3	NDC:65753-400-13	25 in 1 CONTAINER	11/26/2019	
3		1 mL in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:65753-400-14	300 in 1 CONTAINER	11/26/2019	
4		1 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	part348	11/25/2019	

Labeler - CoreTex Products Inc (061944620)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises		017701475	manufacture(65753-400)

Establishment

Name	Address	ID/FEI	Business Operations
CoreTex Products Inc		061944620	label(65753-400)

Revised: 11/2019