CORETEX ANTI-ITCH GEL- camphor, diphenhydramine, zinc acetate gel CoreTex Products Inc

Cortex Anti-Itch Gel 65753-400

Active Ingredients

Camphor 0.1%

Diphenhydramine hydrochloride 2%

Zinc acetate 1%

Purpose

Extrenal analgesic

External analgesic

Skin protectant

Uses

• For the temporary relief of itching and pain associated with minor cuts, minor skin irritations and rashes due to insect bites, poison ivy, poison oak, and 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.
- Avoid contact with the eyes
- more than directed

When using the 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 2 years of age and older: apply to affected area not more than 3 to 4 times daily. **Children under 2 years of age:** do not use, consult 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: (877) 684-5774

Made in USA for CoreTex Products, Inc. Erwin, TN 37650 (877) 684-5774

PRINCIPAL DISPLAY PANEL 65753-400-02







Principal Display Panel 65753-13 and -14

Anti-Itch Gel Pouch







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 | | |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) | DIPHENHYDRAMINE | 2 g | | |

| (DIPHENHYDRAMINE - UNII:8GTS82S83M) | HYDROCHLORIDE | in 100 mL |
|--|---------------------|--------------------|
| ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37) | ZINC ACETATE | 1 g in 100 mL |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 0.1 g in 100 mL |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| METHYLCELLULOSE (1500 CPS) (UNII: PONTE48364) | | | | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| PROPYLENE GLYCOL 1-ALLYL ETHER (UNII: QRB8092KPK) | | | | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | | | | |
| DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4) | | | | |
| METHYLPARABEN (UNII: A218C7H19T) | | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | | |

| 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 Drug | M017 | 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 | pack(65753-400) | |

Revised: 11/2023 CoreTex Products Inc