#### THE ITCH ERASER GEL- diphenhydramine hcl gel Adventure Ready Brands

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.

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### The Itch Eraser Gel

### **Active Ingredient**

Diphenhydramine HCl 2%

### Purpose

**Topical Analgesic** 

### Uses

For the temporary relief of pain and itching associated with

- insect bites
- minor burns
- sunburn
- minor skin irritations
- minor cuts
- rashes due to poison ivy, poison oak, and poison sumac

### Warnings

For external use only

### Do not use

Do not use

- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth

# Ask a doctor before use

Ask a doctor before use

- on chicken pox
- on measles

### When using

When using this product avoid contact with eyes.

# Stop use and ask a doctor if

Stop use and ask a doctor if

- condition worsens
- if symptoms persist for more than 7 days or clear up and occur again within a few days

# Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

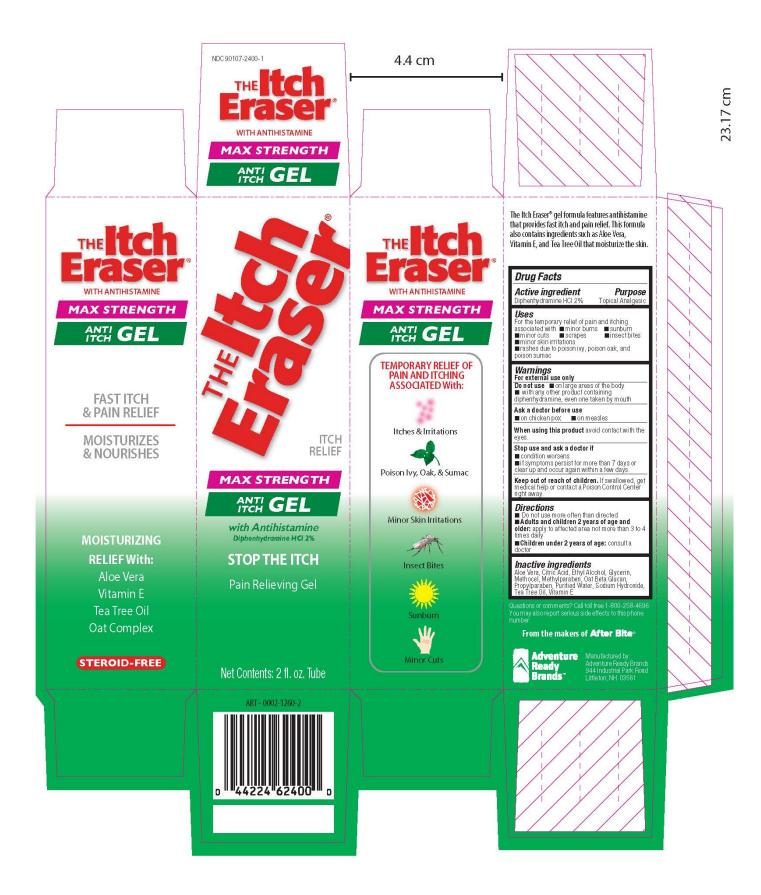
Directions

- do not use more than directed
- adults and children over 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

# **Inactive Ingredients**

Aloe Vera, Citric Acid, Ethyl Alcohol, Glycerin, Methocel, Methylparaben, Oat Beta Glucan, Propylparaben, Purified Water, Sodium Hydroxide, Tea Tree Oil, Vitamin E

# Package Labeling



#### THE ITCH ERASER GEL

diphenhydramine hcl gel

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:90107-2400

| Route | of Administration |  |
|-------|-------------------|--|
|-------|-------------------|--|

| Active Ingredien                           | Active molety                                   |                                      |          |                 |
|--|---|--------------------------------------|----------|-----------------|
|  | Ingredient Name                                 | Basis of St                          | trength  | Strengt         |
| <b>DIPHENHYDRAMINE</b><br>UNII:8GTS82S83M) | HYDRO CHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAM | INE - DIPHENHYDRAMI<br>HYDROCHLORIDH |          | 20 mg<br>in 1 g |
| Inactive Ingredie                          | nts   |                                      |          |                 |
|  | Ingredient Name                                 |                                      | S        | trength         |
| ALOE VERA LEAF (U                          | NII: ZY8 1Z8 3H0 X)                             |                                      |          |                 |
| ANHYDRO US CITRIC                          | ACID (UNII: XF417D3PSL)                         |                                      |          |                 |
| ALCOHOL (UNII: 3K9                         | 958V90M)  |                                      |          |                 |
| PROPYLPARABEN (U                           | NII: Z8IX2SC1OH)                                |                                      |          |                 |
| METHYLPARABEN (U                           | JNII: A218 C7H19 T)                             |                                      |          |                 |
| TEA TREE OIL (UNII:                        | VIF565UC2G)                                     |                                      |          |                 |
| METHYLCELLULOS                             | E (100 CPS) (UNII: 4GFU244C4J)                  |                                      |          |                 |
| OATMEAL (UNII: 8 PIE                       | 4V663Y)   |                                      |          |                 |
| WATER (UNII: 059QF                         | )KO0R)  |                                      |          |                 |
| SO DIUM HYDRO XID                          | E (UNII: 55X04QC32I)                            |                                      |          |                 |
| ALPHATOCOPHER                              | <b>OL ACETATE</b> (UNII: 9E8X80D2L0)            |                                      |          |                 |
| GLYCERIN (UNII: PDC                        | 6A3C0OX)  |                                      |          |                 |
|  |   |                                      |          |                 |
|  |   |                                      |          |                 |
| Packaging                                  |   |                                      |          |                 |
| # Item Code                                | Package Description M                           | arketing Start Date                  | Marketin | ig End Date     |
| <b>1</b> NDC:90107-2400-1                  | 1 in 1 BOX 09                                   | /01/2020                             |          |                 |

| <b>1</b> NDC:90107-2400-1 | 1 in 1 BOX  | 09/01/2020 |
|---------------------------|---|------------|
| 1                         | 57 g in 1 TUBE; Type 0: Not a Combination Product |            |
| <b>2</b> NDC:90107-2400-0 | 57 g in 1 TUBE; Type 0: Not a Combination Product | 09/01/2020 |
|                           |   |            |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part348                                  | 09/01/2020           |                    |  |

Labeler - Adventure Ready Brands (064437304)

**Registrant** - Adventure Ready Brands (064437304)

| Establishment          |         |           |                            |  |  |
|------------------------|---------|-----------|----------------------------|--|--|
| Name                   | Address | ID/FEI    | <b>Business Operations</b> |  |  |
| Adventure Ready Brands |         | 064437304 | manufacture(90107-2400)    |  |  |