

**AMINO ACTIVE TOPICAL ANALGESIC CREAM- histamine  
dihydrochloride cream  
VIREO SYSTEMS, INC.**

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**AMINO ACTIVE Topical Analgesic Cream**

***Drug Facts***

***Active ingredients***

Histamine DHCl 0.025%

***Purpose***

Topical Analgesic

***Uses:***

- For the temporary relief of minor aches and pains of muscles and joints, associated with arthritis, simple back aches, strains, bruises, and sprains.
- Provides penetrating pain relief.

***Warnings:***

***For External Use Only***

**Do not**

- apply to wounds or damaged skin.
- bandage tightly.

**When using this product**

- Avoid contact with eyes.

**Stop use and ask a doctor if**

- condition worsens, 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 a Poison Control Center right away.

**If pregnant or breastfeeding**

ask a health professional before use.

***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: consult a doctor.

**Other Information:**

- Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients:**

Alpha GEE®, Cetyl Alcohol, Colloidal Oatmeal, Dioctyl Sodium Sulfosuccinate, Glyceryl MonoStearate, Polyethylene Glycol, Polyethylene Glycol 400, Polyethylene Glycol 3350, Sodium Hydroxide.

**Package Labeling:**

Histamine DHCl is derived from an essential amino acid. Application to affected area eases pain of muscles and joints.

Relief for muscles, joints, arthritis, backaches, strains, bruises and sprains

**Vireo**

Manufactured in the USA for Vireo Systems, Inc. 305 Williams Ave. Madison, TN 37115 1-855-442-6466 vireosystems.com

**AMINO ACTIVE**

POWERED BY ALPHA-GEE®

**Topical Analgesic Cream**

2.75 fl oz / 81.33 ml

| Drug Facts   |                                     |
|--|-------------------------------------|
| <b>Active Ingredients</b><br>Histamine DHCl 0.025%   | <b>Purpose</b><br>Topical Analgesic |
| <b>Uses:</b> • For the temporary relief of minor aches and pains of muscles and joints, associated with arthritis, simple back aches, strains, bruises, and sprains. • Provides penetrating pain relief.                   |                                     |
| <b>Warnings: For External Use Only</b>   |                                     |
| <b>Do not</b> • apply to wounds or damaged skin. • bandage tightly   |                                     |
| <b>When using this product</b> • Avoid contact with eyes.  |                                     |
| Stop use and ask a doctor if • condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.   |                                     |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breastfeeding ask a health professional before use.                                     |                                     |
| <b>Directions:</b> • 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: consult a doctor.   |                                     |
| <b>Other Information:</b> • Protect the product in this container from excessive heat and direct sun.  |                                     |
| <b>Inactive Ingredients:</b> Alpha GEE®, Cetyl Alcohol, Colloidal Oatmeal, Dioctyl Sodium Sulfosuccinate, Glyceryl MonoStearate, Polyethylene Glycol, Polyethylene Glycol 400, Polyethylene Glycol 3350, Sodium Hydroxide. |                                     |
| <b>PROPRIETARY INGREDIENT</b><br>Alpha-GEE® (ethyl-[ε-guanido-methyl]ethanoate) is a unique peptide compound conjugated. It is a non-essential and conditionally essential amino acids found in natural sources.           |                                     |

**AMINO ACTIVE TOPICAL ANALGESIC CREAM**

histamine dihydrochloride cream

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:82908-357 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength         | Strength        |
|---|---------------------------|-----------------|
| <b>HISTAMINE DIHYDROCHLORIDE</b> (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3) | HISTAMINE DIHYDROCHLORIDE | 0.25 mg in 1 mL |

**Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)                     |          |
| <b>OATMEAL</b> (UNII: 8PI54V663Y)                           |          |
| <b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0)                   |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)             |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDWL1A) |          |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)           |          |
| <b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)          |          |

**SODIUM HYDROXIDE** (UNII: 55X04QC32I)

### Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:82908-357-00 | 81.33 mL in 1 JAR; Type 0: Not a Combination Product | 08/08/2022           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M017                                     | 08/08/2022           |                    |

**Labeler** - VIREO SYSTEMS, INC. (832940295)

Revised: 11/2023

VIREO SYSTEMS, INC.