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

AMINO ACTIVE Topical Analgesic Cream

Drug Facts

Active ingredients

Histamine DHCI 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.

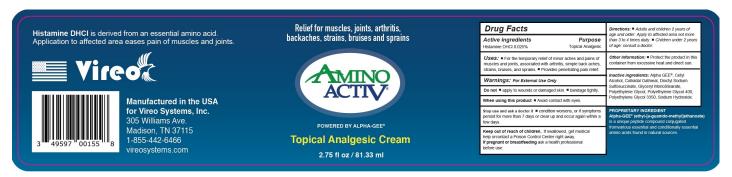
Other Information:

• 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:



AMINO ACTIVE TOPICAL ANALGESIC CREAM

histamine dihydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82908-357
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.25 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CETYL ALCOHOL (UNII: 936JST6JCN)		
OATMEAL (UNII: 8PI54V663Y)		
DOCUSATE SODIUM (UNII: F05Q2T2JA0)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		

CODILINA	LIVERAVIEL	/LINIII.	FFV040C33IV
SUDIUM	HYDROXIDE	(UIVIII:	33XU4UU3ZII

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.