

PAIN RELIEVING ARTHRITIS- histamine dihydrochloride cream

Velocity Pharma LLC

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.

Pain Relieving Arthritis Cream

Drug Facts

Active Ingredient

Histamine dihydrochloride 0.025%

Purpose

External Analgesic

Uses

- For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains & bruises.

Warnings

- **For external use only.**
- **Do not use** on wounds or damaged skin or if you are allergic to ingredients in the product.

When using this product

- avoid contact with eyes. If product gets into eyes, rinse thoroughly with water.
- do not bandage tightly or use a heating pad.

Stop use and ask a doctor if

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

If pregnant or breast feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **For Use by Adults and Children over 12 years.**
- Apply a thin layer to pain site and massage until thoroughly absorbed into skin. Apply no more than 3 to 4 times daily.
- **Children 12 years or younger consult a physician.**

Other information

- Store between 40°F and 86°F (4°C and 30C).
- Tamper Evident Feature: do not use if outer shrink wrap on jar is torn, broken or missing.

Inactive ingredients

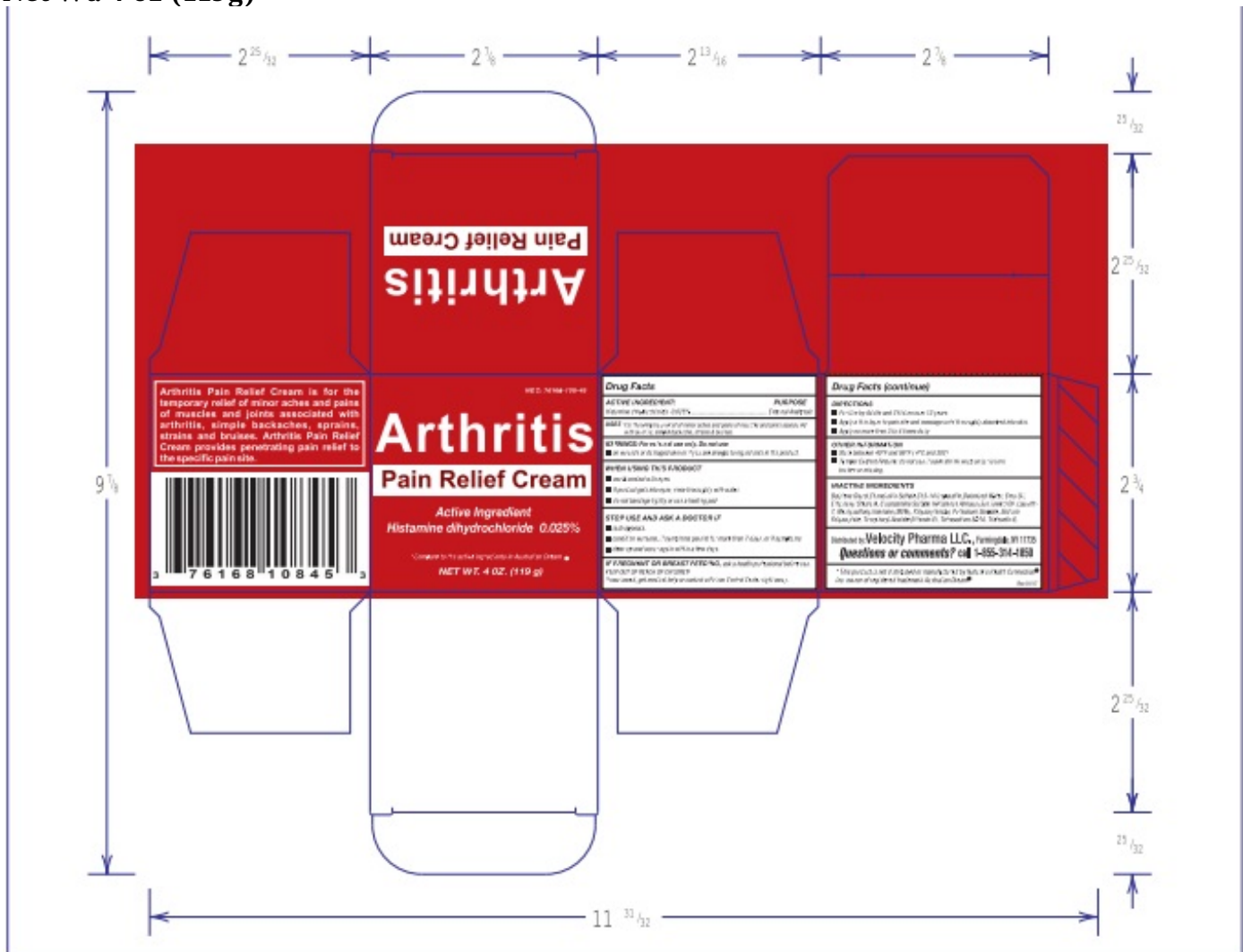
butylated hydroxyl toluene, cetostearyl alcohol , cetomacrogol 1000, cetyl alcohol, disodium EDTA, disodium hydrogen phosphate, light liquid paraffin, propylene glycol, sorbic acid, transquitol P, white petroleum jelly

Questions or Comments? Call 1855-314-1850

Distributed by: Velocity Pharma LLC
 Farmingdale, NY, 11735

Pain Relieving Arthritis Cream

Net Wt. 4 oz (119g)



PAIN RELIEVING ARTHRITIS
 histamine dihydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76168-108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HISTAMINE DIHYDRO CHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISODIUM HYDROGEN CITRATE (UNII: 6FO62KCQ7A)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-108-45	119 g in 1 JAR; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2017	

Labeler - Velocity Pharma LLC (962198409)

Registrant - Velocity Pharma LLC (962198409)

Establishment

Name	Address	ID/FEI	Business Operations
Yash Pharmaceuticals		871409551	manufacture(76168-108)

Establishment

Name	Address	ID/FEI	Business Operations
Velocity Pharma LLC		962198409	label(76168-108)