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- RA

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

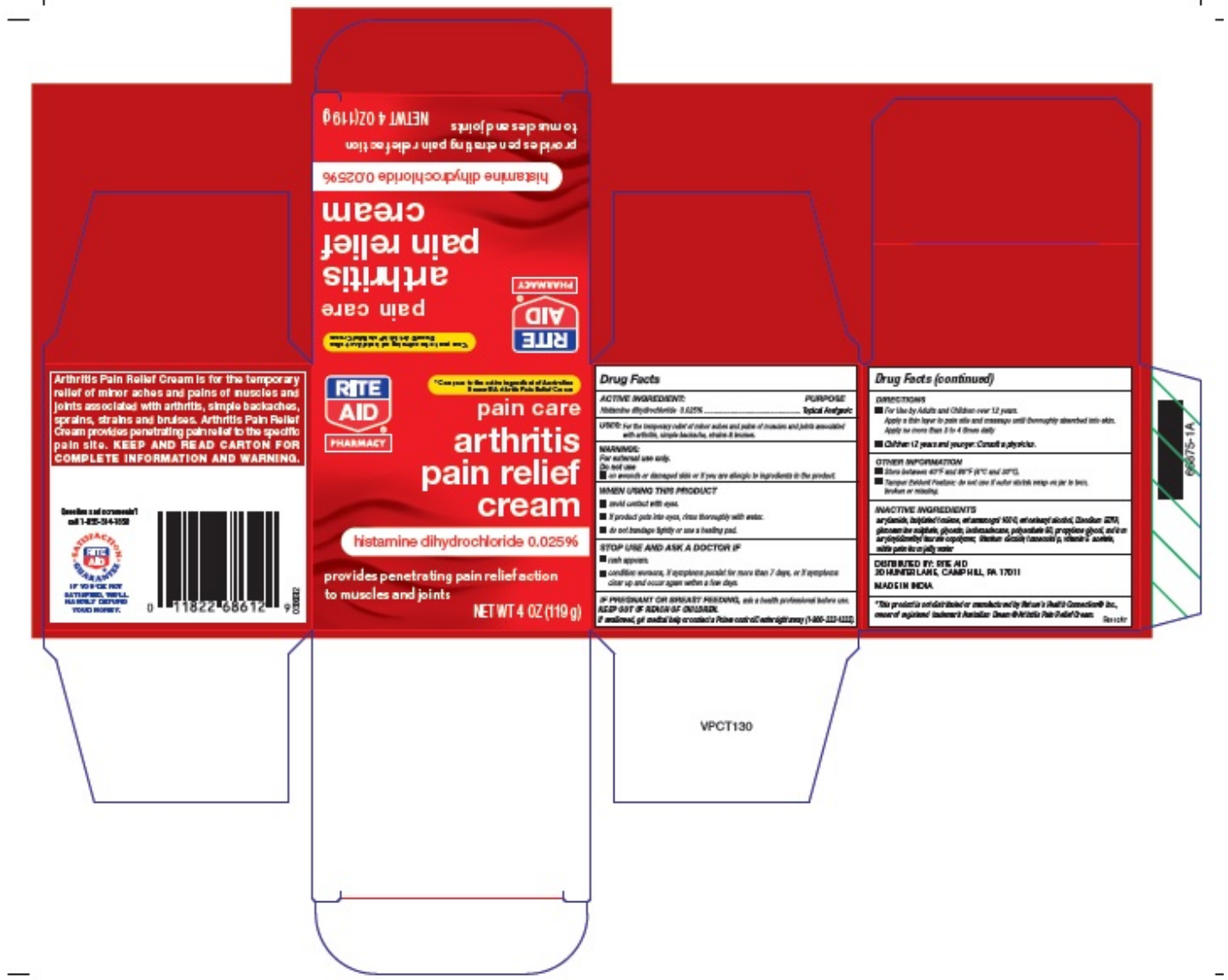
arylamide, butylated hydroxyl toluene, cetostearyl alcohol , cetomacrogol 1000, disodium EDTA, glucosamine sulfate, glycerin, isohexadecane, polysorbate 80, propylene glycol, sodium acrylodimethyl taurate copolymer, titanium dioxide, transquitol P, vitamin E acetate, white petroleum jelly, water

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:76168-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.025 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ACRYLAMIDE (UNII: 20R035KLCI)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DISODIUM HYDROGEN CITRATE (UNII: 6FO62KCQ7A)	
EDETATE SODIUM (UNII: MP1J8420LU)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76168-300-38	119 g in 1 JAR; Type 0: Not a Combination Product	05/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/26/2017	

Labeler - Velocity Pharma LLC (962198409)

Registrant - Velocity Pharma LLC (962198409)

Establishment

Name	Address	ID/FEI	Business Operations
Yash Pharmceuticals		871409551	manufacture(76168-300)

Establishment

Name	Address	ID/FEI	Business Operations
Velocity Pharma LLC		962198409	label(76168-300)

Revised: 5/2017 Velocity Pharma LLC