

DR. FRED'S MIRACLE RUB- histamine dihydrochloride cream
Pure Source, LLC

Dr. Fred's MIRACLE RUB

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Active Ingredients:

Histamine Dihydrochloride 0.025%

Purpose

External Analgesic

Uses:

For temporary relief of minor aches and pains associated with simple backache, arthritis, bruises and sprains.

Warnings:

- For external use only. - Avoid contact with eyes. - Do not apply to open wounds or damaged skin.

- If symptoms

persist for more than seven days, discontinue use and consult physician.

- Keep out of reach of children.

If swallowed, consult physician.

Do not use

if you have a known allergy to any of the ingredients listed. - Do not bandage tightly.

- If pregnant or breast feeding,

contact physician prior to use.

Directions:

Apply directly to affected area. Do not use more than four times per day.

Other Ingredients:

Aloe Barbadensis Leaf (Aloe Vera Juice) Gel, Aqua (Deionized Water), Arnica Montana Extract, Carbomer, C13-14 Isoparaffin, Cetearyl Oliviate, Dimethyl Sulfone (MSM), Laureth-7, Magnesium Sulfate, Parfum (Fragrance), Polyacrylamide, Potassium Sorbate, Royal Jelly, Sodium Benzoate, Sodium Stearate, Sorbitan Oliviate, Stearic Acid, Triethanolamine.

Manufactured for:

Haleivo, Inc. Ojai, Ca 93023 USA www.DrFredsMeds.com

KNOCK OUT PAIN WITH Dr. Fred's MIRACLE RUB OJAI ORIGINAL PATENT PENDING

4 FL. OZ. (118 ML)

Dr. Fred's MIRACLE RUB 4oz/118ml (65121-403-25)

<p>DRUG FACTS: Active Ingredients: Histamine Dihydrochloride 0.025% External Analgesic</p> <p>Uses: For temporary relief of minor aches and pains associated with simple backache, arthritis, bruises and sprains.</p> <p>Warnings: - For external use only. - Avoid contact with eyes. - Do not apply to open wounds or damaged skin. - If symptoms persist for more than seven days, discontinue use and consult physician. - Keep out of reach of children. If swallowed, consult physician. - Do not use if you have a known allergy to any of the ingredients listed. - Do not bandage tightly. - If pregnant or breast feeding, contact physician prior to use.</p>		<p>Directions: Apply directly to affected area. Do not use more than four times per day.</p> <p>Other Ingredients: Aloe Barbadensis Leaf (Aloe Vera Juice) Gel, Aqua (Deionized Water), Arnica Montana Extract, Carbomer, C13-14 Isoparaffin, Cetearyl Oliviate, Dimethyl Sulfone (MSM), Laureth-7, Magnesium Sulfate, Parfum (Fragrance), Polyacrylamide, Potassium Sorbate, Royal Jelly, Sodium Benzoate, Sodium Stearate, Sorbitan Oliviate, Stearic Acid, Triethanolamine.</p> <p>4 FL. OZ. (118 ML) Manufactured for: Haleivo, Inc. Ojai, Ca 93023 USA www.DrFredsMeds.com</p>
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DR. FRED'S MIRACLE RUB			
histamine dihydrochloride cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-403
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N813)	HISTAMINE DIHYDROCHLORIDE	0.25 mg in 1 mL
Inactive Ingredients			

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA (UNII: O80TY208ZW)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
LAURETH-7 (UNII: Z95S6G8201)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ROYAL JELLY (UNII: L497I37F0C)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-403-25	1 in 1 CARTON	02/09/2017	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/06/2013	

Labeler - Pure Source, LLC (080354456)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(65121-403)

Revised: 11/2023

Pure Source, LLC