

RELIEF PAIN RELIEVING CREAM- menthol cream
Corganics, LP

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.

DRUG FACTS

ACTIVE INGREDIENT

Menthol 2.5%

PURPOSE

Counterirritant

USAGE

For the temporary Relief of pain of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

WARNINGS

For external use only. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again in a few days, discontinue use of this product and consult a physician.

Do Not Use

- on wounds or damaged skin
- when bandaged tightly
- with other topical products

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center immediately.

DIRECTIONS

- Adults and children 2 years old and older: apply a small amount to affected area not more than 3 to 4 times daily.
- Gently massage until absorbed.
- Children under 2 years of age: consult a doctor.

INACTIVE INGREDIENTS

Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglycerides, Carbomer, Cetareth-20, Cetearyl Alcohol, Cetyl Alcohol, Citrus Aurantium Dulcis (Sweet Orange) Oil, Cymbopogon Martini (Palmarosa) Oil, Deionized Water, Diazolidinyl Urea, Eucalyptus Globulus Leaf Oil, Glycerine, Iodopropynyl Butylcarbamate, L-Arginine, Lavandula Angustifolia (Lavender) Oil, Lecithin, Mentha Piperita (Peppermint Oil), Tocopherol, Methylsulfonylmethane, Tocopheryl Acetate, Triethanolamine

Pain Relieving Cream
2.5% Menthol
Topical Analgesic



CORGANICS®
The Art in the Science of Nature®

Net Wt 4 oz (115 g)

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Drug Facts	
Active Ingredient Menthol, 2.5%	Purpose Counterirritant
Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.	
Warnings For external use only. Avoid contact with the eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again after a few days, discontinue use of this product and consult a physician.	
Do not use ■ on wounds or damaged skin ■ when bandaged tightly ■ with other topical products	
Stop use and ask a doctor if skin redness or excessive skin irritation occurs.	
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center immediately.	
Directions ■ Adults and children 2 years old and older: apply a small amount to affected area not more than 3 to 4 times daily. ■ Gently massage until absorbed. ■ Children under 2 years of age: consult a doctor.	
Drug Facts (continued)	
Inactive ingredients Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglycerides, Carbomer, Cetareth-20, Cetearyl Alcohol, Cetyl Alcohol, Citrus Aurantium Dulcis (Sweet Orange) Oil, Cymbopogon Martini (Palmarosa), Deionized Water, Diazolidinyl Urea, Eucalyptus Globulus Leaf Oil, Glycerin, Iodopropynyl Butylcarbamate, L-Arginine Monohydrochloride, Lavandula Angustifolia (Lavender) Oil, Lecithin, Mentha Piperita (Peppermint) Oil, Methylsulfonylmethane, Tocopherol, Tocopheryl Acetate, Triethanolamine	
Questions? (214) 654-9060	



RELIEF PAIN RELIEVING CREAM			
menthol cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58559-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 g in 100 g
Inactive Ingredients			

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ORANGE OIL (UNII: AKN3KSD11B)	
PALMAROSA OIL (UNII: 0J3G3O53ST)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARGININE (UNII: 94ZLA3W45F)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58559-001-01	5 g in 1 BLISTER PACK	05/22/2004	
2	NDC:58559-001-02	82 g in 1 BOTTLE, WITH APPLICATOR	05/22/2004	
3	NDC:58559-001-03	115 g in 1 TUBE	05/22/2004	
4	NDC:58559-001-04	450 g in 1 BOTTLE, PUMP	05/22/2004	
5	NDC:58559-001-05	3600 g in 1 BOTTLE, PUMP	05/22/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/22/2004	

Labeler - Corganics, LP (028162522)

Establishment

Name	Address	ID/FEI	Business Operations

Revised: 11/2014

Corganics, LP