

REACTHEAT HEAT BAUME- menthol, capsicum annum extract cream

Rejuvenus

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.

Reactheat Reactivating Heat Baume

Active Ingredients	Purpose
Menthol (5%)	External Analgesic
Capsicum Annum Extract (0.5)	External Analgesic

Uses

For temporary relief of minor aches and pains of muscles such as: simple backache, lumbago, arthritis, neuralgia, strains, bruises and sprains.

Keep out of reach of children

Consult a doctor and discontinue use if condition worsens or persists for more than 7 days.

For external use only. When using this product, avoid contact with eyes. Wash hands completely after each use. If swallowed seek medical assistance immediately or contact poison control. If you are pregnant or nursing, seeking the advice of your doctor before using this product.

Directions for use

Apply cream to sore muscles and joints and massage into skin as needed. For adults and children 2 years of age and older apply to affected area no more than 3 to 4 times daily. Children under 2 years of age consult a doctor.

Water, Dimethyl Sulfone, Clove Bud Oil, Peppermint Oil, Eucalyptus Oil, Aloe vera, Ascorbic Acid, Tocopherol, Glycine, Wintergreen Oil, Jojoba Oil, Arnica Montana Flower Extract, Polyarylamide, C13-14 Isoparaffin, Laureth 7, Sodium Hydroxymethylglycinate, glycerol.

(reactheat)

REACTIVATING HEAT BAUME

DRUG FACTS

ACTIVE INGREDIENTS

PURPOSE

Menthol (5%).....	External Analgesic
Capsicum Annum Extract (.5%).....	External Analgesic

USES

For temporary relief of minor aches and pains of muscles such as: Simple Backache, Lumbago, Arthritis, Neuralgia, Strains, Bruises and Sprains.

WARNINGS

FOR EXTERNAL USE ONLY - KEEP OUT OF REACH OF CHILDREN
When using this product avoid contact with eyes. Wash hands completely after each use. Consult a doctor and discontinue use if conditions worsen or persist for more than 7 days. If swallowed, seek medical assistance immediately or contact Poison Control. If you are pregnant or nursing, seek the advice of your doctor before using this product.

DIRECTIONS FOR USE

Apply cream to sore muscles and joints and massage into skin as needed. For 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.

DRUG FACTS (continued)

OTHER INGREDIENTS

Water, Dimethyl Sulfone, Clove Bud Oil, Peppermint Oil, Eucalyptus Oil, Aloe Vera, Ascorbic Acid, Tocopherol, Glycine, Wintergreen Oil, Jojoba Oil, Arnica Montana Flower Extract, Polyacrylamide, C13-14 Isoparaffin, Laureth 7, Sodium Hydroxymethylglycinate, Glycerol

Made in the USA
Distributed by Rejuventus, Inc.
Chattanooga, TN
1-866-379-3510
www.reactice.com

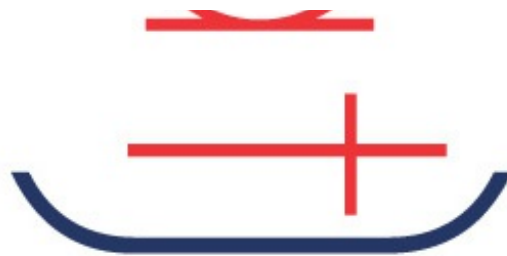


Reactheat
Reactivating Heat Baume

4 fl. oz./ 118.29ml

reodctneo

REACTIVATING HEAT BAUME



external analgesic

4 fl oz./118.29ml

REACTHEAT HEAT BAUME

menthol, capsicum annum extract cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75963-126
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mL in 100 mL
BIRD PEPPER (UNII: J LH5RT8O28) (BIRD PEPPER - UNII:J LH5RT8O28)	BIRD PEPPER	0.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
CLOVE OIL (UNII: 578389D6D0)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCINE (UNII: TE7660XO1C)	
JOJOBA OIL (UNII: 724GKU717M)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75963-126-01	118 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part348		08/20/2011	

Labeler - Rejuvenus (032186703)

Registrant - Rejuvenus (032186703)

Establishment			
Name	Address	ID/FEI	Business Operations
RWM technologies		003215779	manufacture