PAIN THERAPY- menthol, methyl salicylate cream
Renu Laboratories, Inc.

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.

RSD EMU OIL PAIN THERAPY

ACTIVE INGREDIENTS

Menthol 2%

Methyl Salicylate 10%

PURPOSE

Topical Analgesic

Topical Analgesic

USES

Temporarily relieves minor aches and pains of muscle and joints due to: arthritis, simple backache, sprains, strains and bruises

Warnings

For external use only

When using this product

- Do not apply to wounds or damaged skin
- Do not bandage tightly
- Do not use in or near eyes; if product gets into eyes rinse thoroughly with water
- Do not use with an electric heating pad

Stop use and ask doctor if

- Conditions worsen
- Symptoms last for more than 7 days or clear up and occur again within a few days
- A rash or irritation develops

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.

Inactive Ingredients

Allantoin, Benzoic Acid, C13-14 Isoparaffin, Capsicum Frutescens Fruit Extract, Cetearyl Alcohol, Cetearyl Glucoside, Dehydroacetic Acid, Deionized Water, Emu Oil, Eucalyptus Globulus Leaf Oil, Glyceryl Stearate, Laureth-7, Mentha Piperita (Peppermint) Oil, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Stearic Acid.

ARCTIC HEAT

Dual Active Botanical Warming Formula with Emu Oil

Manufactured by:

Renu Labs Inc.

Ivyland, PA 18974

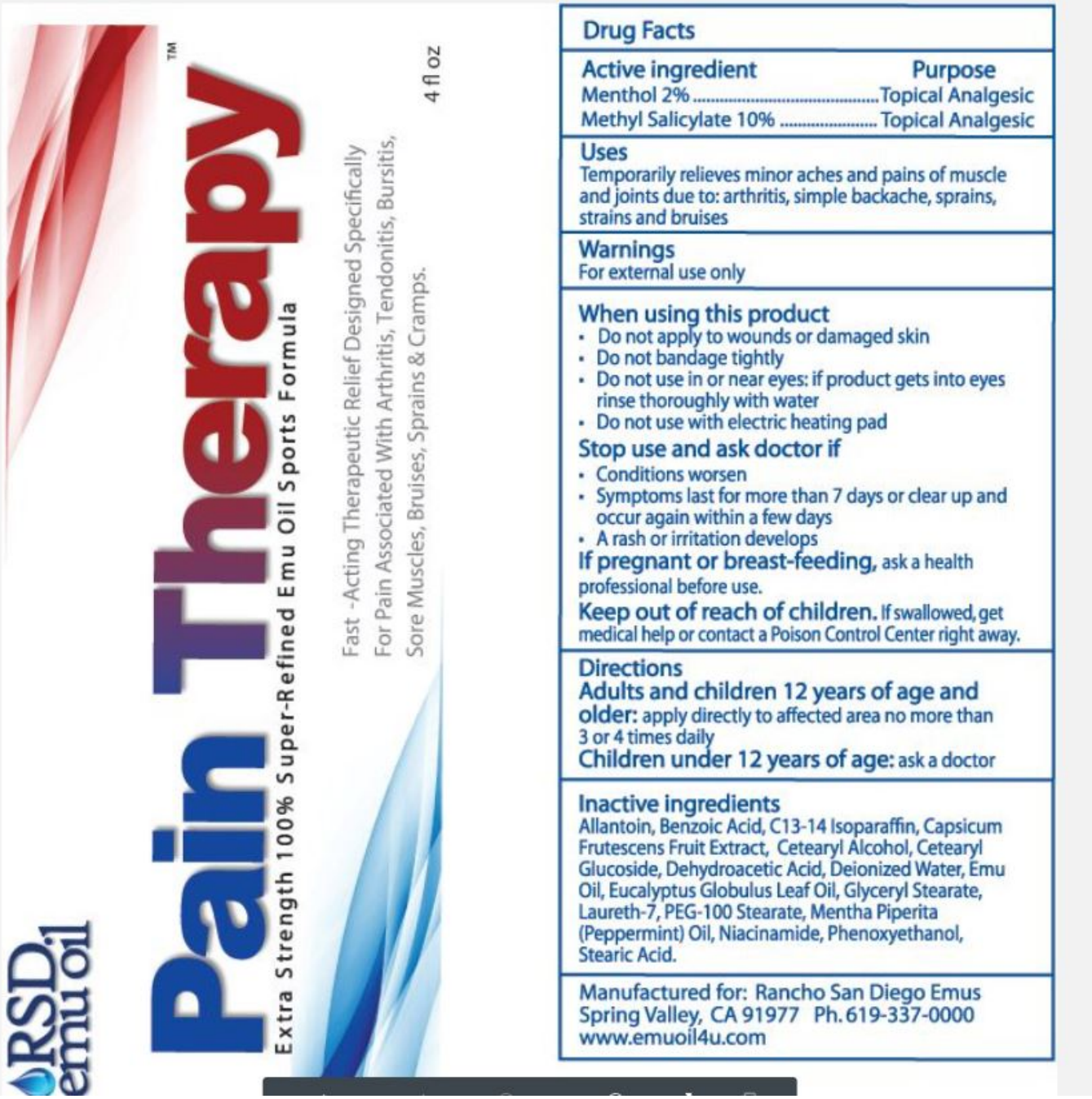
www.RenuLabs.com

Directions

Adults and children 12 years of age and

older: Apply directly to affected area no more than 3 to 4 times daily.

RANCHO SAN DIEGO PAIN RELIEF TUBE



PAIN THERAPY

menthol, methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76348-640
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.24 g in 112 g

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	11.2 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
PEG-100 STEARATE (UNII: YD01N1999R)	
TABASCO PEPPER (UNII: J1M3NA843L)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
LAURETH-7 (UNII: Z95S6G8201)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	
EMU OIL (UNII: 344821WD61)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
WATER (UNII: 059QF0KO0R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-640-04	112 g in 1 TUBE; Type 0: Not a Combination Product	05/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/14/2021	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-640)