OXYRUB MAX PAIN RELIEF CREAM, 20Z- menthol, methyl salicylate cream Healthy Directions, 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.

OxyRub MAX Pain Relief Cream, 2oz

Drug Facts

Active Ingredients

Methol (2.5%)

Methyl Salicylate (10%)

Purpose

Topical Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backaches
- arthritis
- strains
- sprains
- bruises

Warnings

For external use only: **Use only as directed

Do not use

- with a heating pad, may blister skin
- on open wounds or damaged skin

Ask a doctor before use if you have redness over the affected area

When using this product

- avoid contact with eyes
- do not bandage tightly

Stop use and consult a doctor if

- skin redness or excessive skin irritation developments
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again in a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older: Apply to affected area no more than 3-4 times daily. **Children under 12 years of age:** Consult a doctor.

Other information

Store at room termperature. For Lot Number and Expiration Date, see bottom of the carton.

Inactive ingredients C13-14, Insoaraffin,

Citrus Aurantium Dulcis (Organe) Oil,

Ehtylhexlglycerin, Eucalyptus Globulus Oil,

Glyceryl Stearate, Laureth-7, Oxidized Corn

Oil, PEG-100 Stearate, Phenoxyethanol,

Polyacrylamide, Polysorbate-20, Water

Dr. Perigolizzi

OxyRub

MAX

Pain Relief Cream

Extra Strength

Muscle & Joint Pain Relief

Rapidly Absorbed

Deep Penetrating

Distributed by

HEALTHY DIRECTIONS

Bethesda, MD 20817

healthydirections.com



menthol, methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70015-650
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	25.0 mg in 1 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	100.0 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
C13-16 ISOPARAFFIN (UNII: LED42LZG6O)			
ORANGE OIL (UNII: AKN3KSD11B)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
LAURETH-7 (UNII: Z95S6G8201)			
CORN OIL (UNII: 8470G57WFM)			
PEG-100 STEARATE (UNII: YD01N1999R)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
POLYACRYLAMIDE (CROSSLINKED; 0.01-0.2 MOLE PERCENT BISACRYLAMIDE) (UNII: RHA9LWJ494)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:70015-650-02	1 in 1 CARTON	06/01/2017	
ı	1	57 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2017	

Labeler - Healthy Directions, LLC (150261183)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pure Source, LLC		080354456	manufacture(70015-650)	

Revised: 5/2017 Healthy Directions, LLC