PREFERRED PLUS ARTHRITIS CREAM - menthol topical analgesic cream Kinray

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DRUG FACTS

Active Ingredients

Methyl salicylate 15%

Menthol 10%

Capsicum oleoresin (containing capsaicin 0.025%)

Purpose

Topical analgesic

Uses

Uses for the temporary relief of minor aches and pains of muscles and joints associated with

- arthritis
- sprains
- strains
- bruises
- simple backache

Warning

For external use only

Ask Doctor

- condition worsens
- excessive burning or irritation persists
- pain persists for more than 7days
- symptoms clear up and occur again within a few days

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

Directions

- apply to the affective area and gently rub it in until fully absorbed
- repeat asnecessary, but not more than 3 to 4 times daily.

- for best results use continuously for 2 to 4 weeks
- avoid washing treated area for at least 30 minutes after application
- unless treating hands, wash hands thoroughly with soap and water immediately after use

Children under 12

consult a doctor

Inactive ingredients

Water, Stearic Acid, Glyceryl Stearate SE, PEG-40 Stearate, Steareth-2, Triethanolamine, Carbomer, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben.

Front Top



FOLD PROOF ALONG DOTTED LINE to simulate an actual printed label layout



Back Top

PREFERRED PLUS ARTHRITIS CREAM

menthol topical analgesic cream

Product Information			
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:61715-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	15 g in 100 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g		
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
STEARETH-2 (UNII: V56DFE46J5)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-032-02	58 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/23/2001	

Labeler - Kinray (012574513)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment				
Name	Address	ID/FEI	Business Operations	
Reese Pharmaceutical Co		004172052	relabel(61715-032), repack(61715-032)	

Revised: 3/2013 Kinray