

KOFAL FUERTE- methyl salicylate ointment
Pharmadel LLC

Kofal Fuerte Rojo 4 Oz (WP)(DA)

Drug Facts

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Active ingredient and Purpose

Active ingredient

Mythyl Salicylate 15%

Purpose

Topical analgesic

Use

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

- backaches
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only. Avoid contact with the eyes

Do not

- apply to wounds or damaged skin
- bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or 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 immediately.

Directions

- **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

Other information

- store in a cool dry place between (59-86°F)15-30°C
- don't use if seal over jar is broken, torn, or missing

Inactive ingredients

Principal Display Panel

KOFAL ® Fuerte

Deportistas - Athletes

Pain relieving ointment

Pomada analgesico

4 oz (113 g)



KOFAL FUERTE

methyl salicylate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-107
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

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
PARAFFIN (UNII: I9O0E3H2ZE)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CAMPHOR, (-)- (UNII: 213N3S8275)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-107-04	113 g in 1 JAR; Type 0: Not a Combination Product	12/03/2015	10/01/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/03/2015	10/01/2027

Labeler - Pharmadel LLC (030129680)

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Pharmadel LLC