

**KOFAL ORIGINAL- methyl salicylate ointment
Pharmadel LLC**

Kofal Original Blue 4 Oz (WP)(DA)

DRUG FACTS

Active ingredient and Purpose

Active ingredient Purpose

Methyl salicylate 12%.....External analgesic

Uses

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

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only. Avoid contact with the eyes

Do not use

- on wounds or damaged skin

When using this product

- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days

If pregnant or breast feeding,

ask a health professional before use.

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Keep out of reach of children.

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

Directions

- **adults and children 12 years of age and older:** apply to affected area not more than 3 to 4 times daily
- **children under 12 years of age:** do not use, consult a doctor

Other information

- store between 59-86°F (15-30°C)
- do not use if seal over cap is broken, torn, or missing

Inactive ingredients

camphor, cetostearyl alcohol, eucalyptus oil, glyceryl monostearate, menthol, methylparaben, paraffin, polysorbate 20, propylparaben, stearic acid, trolamine, water



KOFAL ORIGINAL

methyl salicylate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	12 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PARAFFIN (UNII: I9O0E3H2ZE)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CAMPHOR, (-)- (UNII: 213N3S8275)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-108-04	113 g in 1 JAR; Type 0: Not a Combination Product	12/03/2015	07/01/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/03/2015	07/01/2027

Labeler - Pharmadel LLC (030129680)