

KOFAL- methyl salicylate ointment
Pharmadel LLC

Kofal Fuerte Ointment 2 oz (WP)(DA)

DRUG FACTS

Active Ingredient and Purpose

Active ingredient Purpose

Methyl salicylate 10.5%.....External analgesic

Uses

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

- simple backache
- arthritis
- strains
- 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.

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, D&C yellow #11, lanolin, menthol, paraffin, petrolatum, propylparaben

Questions or comments?

+1-866-359-3478 M-F 9 AM - 5 PM EST or www.pharmadel.com



KOFAL			
methyl salicylate ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-109
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR, (-)- (UNII: 213N3S8275)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-109-02	60 g in 1 JAR; Type 0: Not a Combination Product	01/21/2020	07/01/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/21/2020	07/01/2027

Labeler - Pharmadel LLC (030129680)

Revised: 12/2025

Pharmadel LLC