

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

Kofal Original Azul (KENIL)

Drug Facts

Drug Facts

Active ingredient and Purpose

<i>Active ingredient</i>	<i>Purpose</i>
Mythyl Salicylate 12%.....	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 clear seal over jar is broken, torn, or missing

Inactive ingredients

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

Principal Display Panel

KOFAL ® Original

Penetrating pain relieving ointment

Pomada analgesica con accion penetrante

4 oz (113 g)



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
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
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 OIL (UNII: 75IZZ8Y727)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

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	

Marketing Information

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

Labeler - PHARMADEL LLC (030129680)

Revised: 3/2024

PHARMADEL LLC