

**KOFAL- methyl salicylate ointment  
Pharmadel LLC**

-----  
**Kofal Fuerte Ointment 2 oz (KENIL)**

***Active ingredients & Purpose***

**Purpose**

External Analgesic

---

***Active ingredient***

Methyl Salicylate 10.5%.....

***Purpose***

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 broken or irritated skin
- with a tight bandage
- with a heating pad

**Stop use and ask doctor immediately if**

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

**If pregnant or breast-feeding,**

ask a health care 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: consult a doctor

**Other information**

- store between 59° to 86°F (15° to 25°C)
- do not use if clear seal over jar is broken, torn or missing

**Inactive ingredients**

camphor, menthol, methylparaben, paraffin, petrolatum, propylparaben.

**Questions or comments?**

**1-866-359-3478** M-F 9 AM - 5 PM EST or [www.pharmadel.com](http://www.pharmadel.com)

**Distributed by/ Distribuido por:**

Pharmadel LLC, Georgetown, DE 199747

**Package Label & Principal Display Panel**



**KOFAL**

methyl salicylate ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55758-109
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10.5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CAMPHOR, (-)-</b> (UNII: 213N3S8275)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

## 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	

## Marketing Information

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

**Labeler** - Pharmadel LLC (030129680)

Revised: 4/2024

Pharmadel LLC