

**KOFAL MAX POWER- menthol ointment  
Pharmadel LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Kofal Max Power Menthol 1.25% (WP)**

***Drug Facts***

***Active ingredient & Purpose***

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<b><i>Active ingredient</i></b>	<b><i>Purpose</i></b>
Menthol 1.25% .....	External analgesic

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***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***

- apply on wounds or irritated skin
- bandage tightly

**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

**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:** do not use, consult a doctor

## Other information

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

## Inactive ingredients

alcohol, arnica montana flower, cannabis sativa (hemp) seed oil, camphor, carbomer 940, DMDM hydantoin, eucalyptus oil, isopropyl alcohol, nonoxynol-9, polysorbate 20, propylene glycol, tea tree oil, trolamine, water

## Distributed by:

**Pharmadel LLC**

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## Principal Display Panel



## KOFAL MAX POWER

menthol ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55758-376
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	1.25 g in 100 g	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
<b>NONOXYNOL-9</b> (UNII: 48Q180SH9T)				
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)				
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)				
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)				
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)				
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)				
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)				
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)				
<b>ALCOHOL</b> (UNII: 3K9958V90M)				
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)				
<b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)				
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)				
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-376-05	142 g in 1 JAR; Type 0: Not a Combination Product	06/10/2023	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/10/2023		

**Labeler** - Pharmadel LLC (030129680)

Revised: 6/2023

Pharmadel LLC