# COCA LIEF- menthol, methylsalicylate gel INDUSTRIA QUIMICO FARMACEUTICA SIGMA CORP. S.R.L.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

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#### **COCA LIEF**

# **Active Ingredients**

Menthol ............ 1.5 mg ..... Topical Analgesic Methyl Salicylate 12.5 mg ..... Topical Analgesic

# **Purpose**

Temporary relief of aches and pains associated with <Arthritis, Carpal Tunnel, Swelling, Sprains, Brusing and Inflamation

If you are pregnant, nursing, or have a medical condition consult a healthcare professional before use.

For External Use Only

If pregnant or breastfeeding consult a healthcare professional before use.

Keep out of reach of children.

Stop use and consult a doctor if condition worsens or if sympotoms last for more than 7 days, or if condition clears up but occurs again a few days later, or if you dicsover a rash/irritation.

Store at 66 to 92 degress Farenheit. Do not leave in direct sunlight.

aPPLY 3 TO 4 TIMES DAILY AS NEEDED

# **Inactive Ingredients**

Trolamine, 95% Isopropyl Alcohol, cellulose, Gycerine, Coca-leaf extract.



# **COCA LIEF**

menthol, methylsalicylate gel

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:84831-096

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL MENTHOL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	401 mg in 100000 mg			
HYDROXYPROPYLCELLULOSE (UNII: 9XZ8H6N6OH)	800 mg in 100000 mg			
CARBOMER 940 (UNII: 4Q93RCW27E)	1000 mg in 100000 mg			
ERYTHROXYLUM COCA LEAF (UNII: D052HE394V)	500 mg in 100000 mg			
WATER (UNII: 059QF0KO0R)	60999 mg in 100000 mg			
METHYLPARABEN (UNII: A2I8C7HI9T)	100 mg in 100000 mg			
TROLAMINE (UNII: 903K93S3TK)	300 mg in 100000 mg			

Product Characteristics				
Color	green	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:84831- 096-01	100000 mg in 1 TUBE; Type 0: Not a Combination Product	01/20/2025	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	01/20/2025		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

# **Labeler -** INDUSTRIA QUIMICO FARMACEUTICA SIGMA CORP. S.R.L. (815366311)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
INDUSTRIA QUIMICO FARMACEUTICA SIGMA CORP. S.R.L.		815366311	manufacture(84831-096)		

Revised: 1/2025 INDUSTRIA QUIMICO FARMACEUTICA SIGMA CORP. S.R.L.