

MAMISAN- lidocaine hydrochloride, menthol ointment
Miramar Cosmetics, Inc DBA Miramar Lab

Mamisan®

Drug Facts

Active ingredients

Lidocaine HCl 4%

Menthol 1%

Purpose

Pain relieving

Use

- For the temporary relief of pain

Warnings

For external use only.

When using this product

- avoid contact with the eyes • do not use in large quantities, particularly over raw surfaces or blistered areas

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 68-77°F (23-25°C)

Inactive ingredients

BHT, D&C Red #17, D&C Yellow #11, Eucalyptus Oil, Petrolatum, Soybean Oil, Wax.

MAX STRENGTH

Distributed by: Plantimex Distributors Inc

7577 Airway Rd #105,

San Diego, CA 92154

To report a serious adverse event, contact the distributor at the address above

Packaging

Mamisan®
PAIN RELIEVING OINTMENT
Lidocaine HCl 4% Menthol 1%
MAX STRENGTH
Net.Wt. 3.52 oz (100 g)

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Drug Facts (continued)
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NDC:79974-216-03

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MAMISAN

lidocaine hydrochloride, menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79974-216
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
D&C RED NO. 17 (UNII: ND733RX3JN)	
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
SOYBEAN OIL (UNII: 241ATL177A)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79974-216-03	100 g in 1 JAR; Type 0: Not a Combination Product	09/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/02/2024	

Labeler - Miramar Cosmetics, Inc DBA Miramar Lab (012873243)

Establishment

Name	Address	ID/FEI	Business Operations
Miramar Cosmetics, Inc DBA Miramar Lab		012873243	manufacture(79974-216)

Revised: 8/2024

Miramar Cosmetics, Inc DBA Miramar Lab