

DZUL - LIDO CREME MAXIMUM STRENGTH- lidocaine, menthol lotion
Caball Sales, Inc.

83037-423-02

Lidocaine 4%

Menthol 2.3%

Topical Analgesic

USES:

For temporary local relief of minor pain in muscles or joints.

For external use only.

Use only as directed.

Avoid contact with eyes and mucous membranes.

Do not bandage tightly or use with a heating pad.

A transient burning sensation or redness may occur upon application but generally disappears in several days.

Do not apply on large areas of the body or on damaged, broken, or irritated skin.

If swallowed, get medical help or contact a Poison Control Center right away.

Ask a health professional before use.

STOP USE AND ASK A DOCTOR IF:

Redness is present.

Condition worsens.

Irritation develops.

Symptoms persist for more than 7 days or clear up and occur again within a few days.

You experience signs injury, such as pain, swelling or blistering where the product was applied.

DIRECTIONS:

Apply a small amount on the affected area.

Massage in a circular motion, let set for a few seconds.

Repeat as necessary, but no more than 3 to 4 times daily.

Store tightly closed in a dry place at room temperature.

Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Isopropyl Myristate, Glycol Stearate, Stearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Sodium Lauryl Sulfate, Dimethicone, Glycerin, Caprylhydroxamic Acid, Caprylyl Glycol, Eucalyptus Globulus Leaf Oil, Phenoxyethanol, Methylpropanediol, Acrylamide/Sodium Acrylate Copolymer, Paraffinum Liquidum, Trideceth-6, Methylsulfonylmethane, Aloe Barbadensis (Aloe Vera) Leaf Juice, Rosmarinus Officinalis (Rosemary) Oil, Tocopheryl Acetate, Arnica Montana

Flower Extract, Salix Alba Bark Extract, Glucosamine Sulfate, Chamomilla Recutita (Matricaria) Flower Extract, Capsicum Annuum Fruit Extract.

NDC 83037-423-02

PAIN RELIEVING



MAXIMUM STRENGTH

**LIDO
CREME**

LIDOCAINE HCL 4 % - MENTHOL 2.3 %




NET WT 2.5 OZ (71 g)

Drug Facts

Active Ingredient:	Purpose
Lidocaine 4 %	Topical Analgesic
Menthol 2.3 %	Topical Analgesic

Uses: For temporary local relief of minor pain in muscles or joints.

Warnings: For external use only.

When using this product: ■ Use only as directed. ■ Avoid contact with eyes and mucous membranes. ■ Do not bandage tightly or use with a heating pad. ■ A transient burning sensation or redness may occur upon application but generally disappears in several days. ■ Do not apply on large areas of the body or on damaged, broken, or irritated skin.

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

If pregnant or breast - feeding: Ask a health professional before use.

Stop use and ask a doctor if: ■ Redness is present. ■ Condition worsens. ■ Irritation develops. ■ Symptoms persist for more than 7 days or clear up and occur again within a few days. ■ You experience signs injury, such as pain, swelling or blistering where the product was applied.

Directions:
Adults and Children over 12 years:
 ■ Apply a small amount to the affected area.
 ■ Massage in a circular motion, let set for a few seconds.
 ■ Repeat as necessary, but no more than 3 to 4 times daily.
 ■ Store tightly closed in a dry place at room temperature.

Inactive Ingredients: Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Isopropyl Myristate, Glycol Stearate, Stearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Sodium Lauryl Sulfate, Dimethicone, Glycerin, Caprylhydroxamic Acid, Caprylyl Glycol, Eucalyptus Globulus Leaf Oil, Phenoxyethanol, Methylpropanediol, Acrylamide/Sodium Acrylate Copolymer, Paraffinum Liquidum, Trideceth-6, Methylsulfoniummethane, Aloe Barbadensis (Aloe Vera) Leaf Juice, Rosmarinus Officinalis (Rosemary) Oil, Tocopheryl Acetate, Arnica Montana Flower Extract, Salix Alba Bark Extract, Glucosamine Sulfate, Chamomilla Recutita (Matricaria) Flower Extract, Capsicum Annuum Fruit Extract.



Distributed by:
DZUL PHARMACEUTICAL, LLC
 FL, 33054 USA
 Questions: (305)-900-8256

DZUL - LIDO CREME MAXIMUM STRENGTH

lidocaine, menthol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83037-423
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.3 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE 1000 (UNII: MCU2324216)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
MINERAL OIL (UNII: T5L8T28FGP)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
CAPSICUM ANNUUM WHOLE (UNII: 7FKZ3QQQ1F)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83037-423-02	71 g in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	10/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/17/2022	04/28/2025

Labeler - Caball Sales, Inc. (047422138)