

ZCAINE FAST ACTING ANESTHETIC- lidocaine gel
PHI, Inc

Zcaine Fast Acting Anesthetic Gel

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Drug Facts

Active Ingredients

Lidocaine 4%

Purpose

Topical Anesthetic

Uses:

For the temporary relief of discomfort and pain associated with

- minor burns and skin irritations
- minor cuts and scrapes
- itching

Warnings:

For external use only.

Avoid contact with eyes.

In large quantities, particularly over raw surfaces or blistered areas **Do not use**

Stop use and ask a doctor if

- skin becomes irritated
- condition worsens or symptoms last more than 7 days
- symptoms clear up and reoccur within a few days

Keep out of reach of children

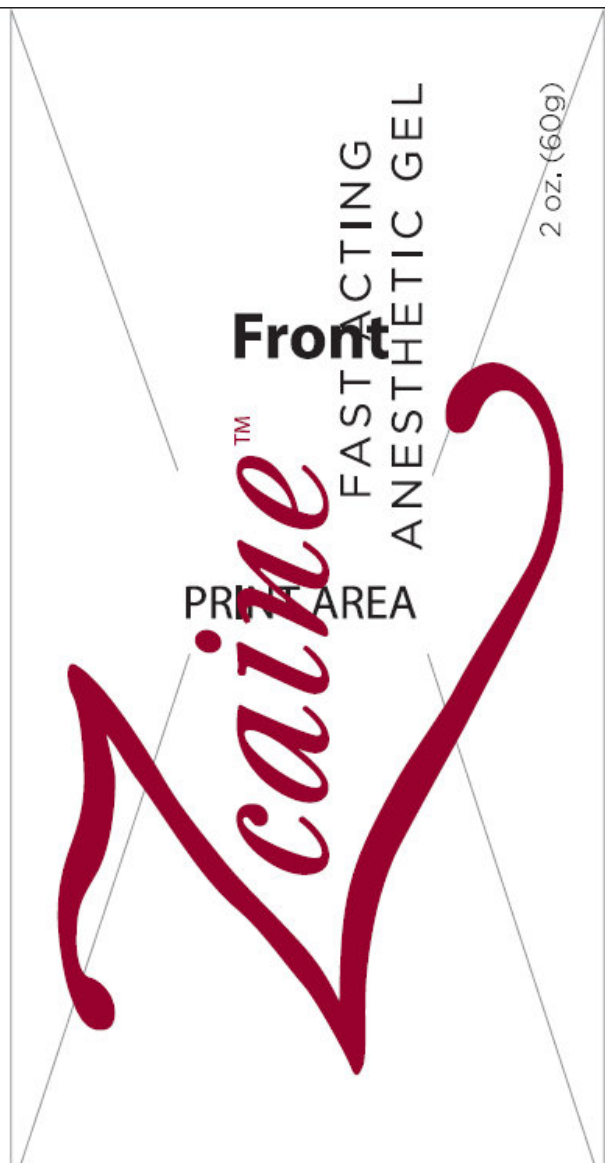
Directions

Adults and children 12 years of age or older: Apply to affected area not more than 3 to 4 times daily.

Other Ingredients:

Aloe Barbadensis Leaf Juice, Calendula Officinalis Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Chamomilla Recutita (Matricaria) Flower Extract, Diazolidinyl Urea, Disodium EDTA, Glycerin, Menthol, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, SD Alcohol 40-2, Symphytum Officinale (Comfrey) Leaf Extract, Triethanolamine

Zcaine Fast Acting Anesthetic Gel 2oz/60g

 <p>Front</p> <p>Zcaine™</p> <p>FAST ACTING ANESTHETIC GEL</p> <p>2 oz. (60g)</p> <p>PRINT AREA</p>	<p>Zcaine™ Fast Acting Anesthetic Gel is effective when used for pain relief of minor burns and skin irritations.</p> <p>ZCAINE™ TOPICAL ANESTHETIC GEL Active Ingredient: Lidocaine 4%</p> <p>Back</p> <p>Warnings: For external use only. Avoid contact with eyes.</p> <p>Directions: Apply Zcaine™ to affected areas not more than 3-4 times daily. Do not use in large quantities, particularly over raw surfaces or blistered areas.</p> <p>PRINT AREA</p> <p>Other Ingredients: Aloe Barbadensis Leaf Juice, Calendula Officinalis Flower Extract, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Chamomilla Recutita (Matricaria) Flower Extract, Diazolidinyl Urea, Disodium EDTA, Glycerin, Menthol, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, SD Alcohol 40-2, Symphytum Officinale (Comfrey) Leaf Extract, Triethanolamine</p> <p>Manufactured exclusively for: PHI, Incorporated, Chesapeake, VA 23320 www.Zcaine.com 757-436-4774</p>
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Other Information
Questions or Comments? Call 757-436-4774 or visit www.Zcaine.com

Manufactured exclusively for:
PHI, Inc.
Chesapeake, VA 23320

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Zcaine™

FRONT
PANEL

FAST ACTING
ANESTHETIC GEL

2 oz. (60g)

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ZCAINE FAST ACTING ANESTHETIC

lidocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27789-911
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
COMFREY LEAF (UNII: DG4F8T839X)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27789-911-02	60 g in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/04/2012	

Labeler - PHI, Inc (611203035)

Registrant - Filltech USA, LLC (965596435)

Establishment

Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		926433855	manufacture(27789-911)

Revised: 11/2023

PHI, Inc