

LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride gel

Safetec of America, Inc.

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.

Burn Gel

Pain Relief

Drug Facts

Active Ingredient

Lidocaine HCl 2.0%

Purpose

Topical pain relief

Uses

Temporary pain relief for minor burns

Warnings

For external use only

Do not use

- In large quantities, particularly over raw or blistered areas
- near eyes, if this happens rinse thoroughly with water

Stop use and ask doctor if condition worsens or persists for more than 7 days or clears up and occurs 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

- for adults and children 2 years and older: apply to affected area not more than 4 times daily
- children under 2: do not use, consult a doctor

Inactive ingredients

aloe vera, carbomer, germaben II, propylene glycol, purified water, menthol, triethanolamine, vitamin E acetate

PRINCIPAL DISPLAY PANEL – 0.125 oz. packet

NDC 61010-5000-0

Safetec

Burn Gel

For Temporary
Pain Relief of
Minor Burns

0.125 oz. (3.7 ml)

Reorder no. 50000

Manufactured by
SAFETEC OF AMERICA, Inc.
Buffalo, NY 14215
800-456-7077
www.safetec.com

NDC 61010-5000-0



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Drug Facts

Active ingredient	Purpose
Lidocaine HCl (2.0%).....	Topical Pain Relief

Uses Temporary pain relief for minor burns ▶

Drug Facts (continued)

Warnings

For external use only

Do not use ■ in large quantities, particularly over raw or blistered areas ■ near eyes, if this happens rinse thoroughly with water

Stop use and ask a doctor if condition worsens or persists for more than 7 days or clears up and occurs 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 and older: apply to affected area not more than 4 times daily ■ children under 2: do not use, consult a doctor

Inactive ingredients

aloe vera, carbomer, germaben II, propylene glycol, purified water, menthol, triethanolamine, vitamin E acetate

PRINCIPAL DISPLAY PANEL – 4 oz. bottle

NDC 61010-5000-4

Safetec

First Aid
Burn Gel

For Temporary
Pain Relief of
Minor Burns

4 fl. oz. (118 ml)
 Reorder no. 50001

NDC 61010-5000-1



First Aid

Burn Gel

For Temporary
 Pain Relief of
 Minor Burns

4 fl. OZ. (118ml)
 Reorder no. 50001

Drug Facts

Active Ingredients	Purpose
Lidocaine HCl 2.0%	Topical pain relief

Uses Temporary pain relief for minor burns

Warnings

For external use only

Do not use

- in large quantities, particularly over raw or blistered areas
- near eyes, if this happens rinse thoroughly with water

Keep out of reach of children

Caution

- if condition worsens or persists for more than 7 days or clears up and returns, discontinue use and consult a physician
- if swallowed get medical help or contact Poison Control Center right away

Directions

- for adults and children 2 years of age or older: apply to affected area not more than 3-4 times per day
- for children under 2 years of age: do not use, consult a physician

Inactive Ingredients

aloe vera, carbomer, germaben II, menthol, propylene glycol, purified water, triethanolamine, vitamin E acetate

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LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:61010-5000
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (Lidocaine)	Lidocaine Hydrochloride	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf	
propylene glycol	
diazolidinyl urea	

water	
menthol	
.alpha.-tocopherol acetate	
trolamine	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-5000-0	3.3 g in 1 PACKET		
2	NDC:61010-5000-1	121.2 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2012	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(61010-5000)

Revised: 10/2012

Safetec of America, Inc.