

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

Safetec

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	

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

Principal Display Panel - Pouch label

Safetec

Burn Gel

0.9 g (1/32 oz.)

Safetec of America, Inc.

Buffalo, NY 14215

800-456-7077



Burn Gel

0.9 g (1/32 oz.)

Safetec of America, Inc.
Buffalo, NY 14215
800-456-7077

Drug Facts

Active Ingredient	Purpose
Lidocaine HCl 2.0%	Topical pain relief

Uses Temporary pain relief for minor burns

Warning
External use only. Keep out of reach of children. ►

Drug Facts (continued)

Warning (continued)

Do not use ■ near eyes, if this happens, rinse thoroughly with water ■ in large quantities, particularly over raw or blistered areas **Stop use, ask a doctor** ■ if conditions worsen or last more than 7 days or clears up and returns. If ingested contact a poison control center directly

Directions ■ adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily ■ children under 2: do not use, ask a doctor

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

Principal Display Panel - 144 Box label

NDC 61010-5000-04

Safetec

First Aid

Burn Gel

For Temporary Pain Relief
of Minor Burns

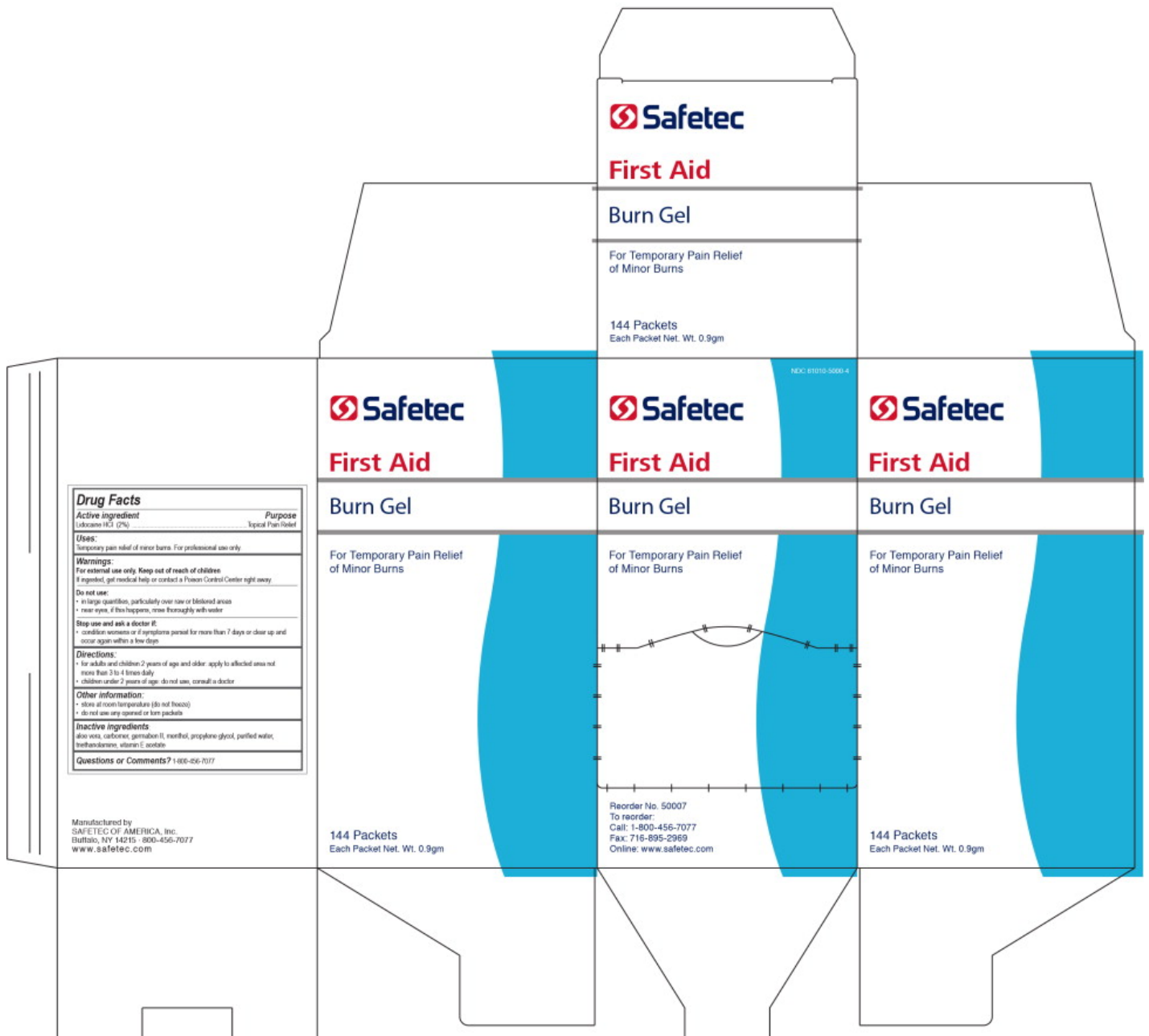
Reorder No. 50007

To reorder:

Call: 1-800-456-7077

Fax: 716-895-2969

Online: www.safetec.com



Principal Display Panel - 25 Box label

NDC 61010-5000-5

Safetec

First Aid

Burn Gel

For Temporary Pain Relief
of Minor Burns

25 Packets

Each Packet Net. Wt. 0.9gm

Burn Gel

First Aid

Safetec

Safetec

Drug Facts

Active ingredients **Purpose**
Lidocaine HCl (2%) Topical Pain Relief

Uses

Temporary pain relief of minor burns. For professional use only.

Warnings

For external use only. Keep out of reach of children.

If ingested, get medical help or contact a Poison Control Center directly.

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

- the condition worsens or if symptoms persist for

Drug Facts (continued)

Warnings (continued)
more than 7 days or clear up and occur again within a few days

Directions

Adults and children 2 years and over: apply to affected area not more than 3 to 4 times daily
Children under 2 years: do not use, consult a doctor

Other information

- store at room temperature (do not freeze)
- do not use any opened or torn packets

Inactive ingredients

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

Questions or Comments? 1-800-456-7077

Manufactured by
SAFETEC OF AMERICA, Inc.
Buffalo, NY 14215
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www.safetec.com

NDC 61010-5000-5

Pull up and tear off



First Aid

Burn Gel

For Temporary Pain Relief
of Minor Burns

25 Packets
Each Packet Net. Wt. 0.9gm

to dispense



Burn Gel

Reorder No. 50006
To reorder:
Call: 1-800-456-7077
Fax: 716-895-2969
Online: www.safetec.com

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride gel

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
propylene glycol (UNII: 6DC9Q167V3)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
water (UNII: 059QF0K00R)	
menthol (UNII: L7T10EIP3A)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-5000-0	3.3 g in 1 PACKET; Type 0: Not a Combination Product	09/19/2012	
2	NDC:61010-5000-1	121.2 g in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2012	
3	NDC:61010-5000-3	0.9 g in 1 POUCH; Type 0: Not a Combination Product	09/19/2012	
4	NDC:61010-5000-4	144 in 1 CARTON	09/19/2012	
4		0.9 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:61010-5000-5	25 in 1 CARTON	09/19/2012	
5		0.9 g in 1 POUCH; Type 0: Not a Combination Product		

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: 2/2017

Safetec of America, Inc.