

BURN JEL- gel for burns gel
NORTH BURN JEL- gel for burns gel
Honeywell Safety Products USA, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

0498-0203. 0498-0200 & 0498-0202: Burn Jel

Active ingredient

Lidocaine HCl 2.0 %

Purpose

External analgesic

Uses

temporarily relieves pain due to minor burns

Warnings

For external use only

Do not use

- on large areas of the body, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs 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: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

Other information

- store at room temperature
- do not use if opened or torn

Inactive ingredients

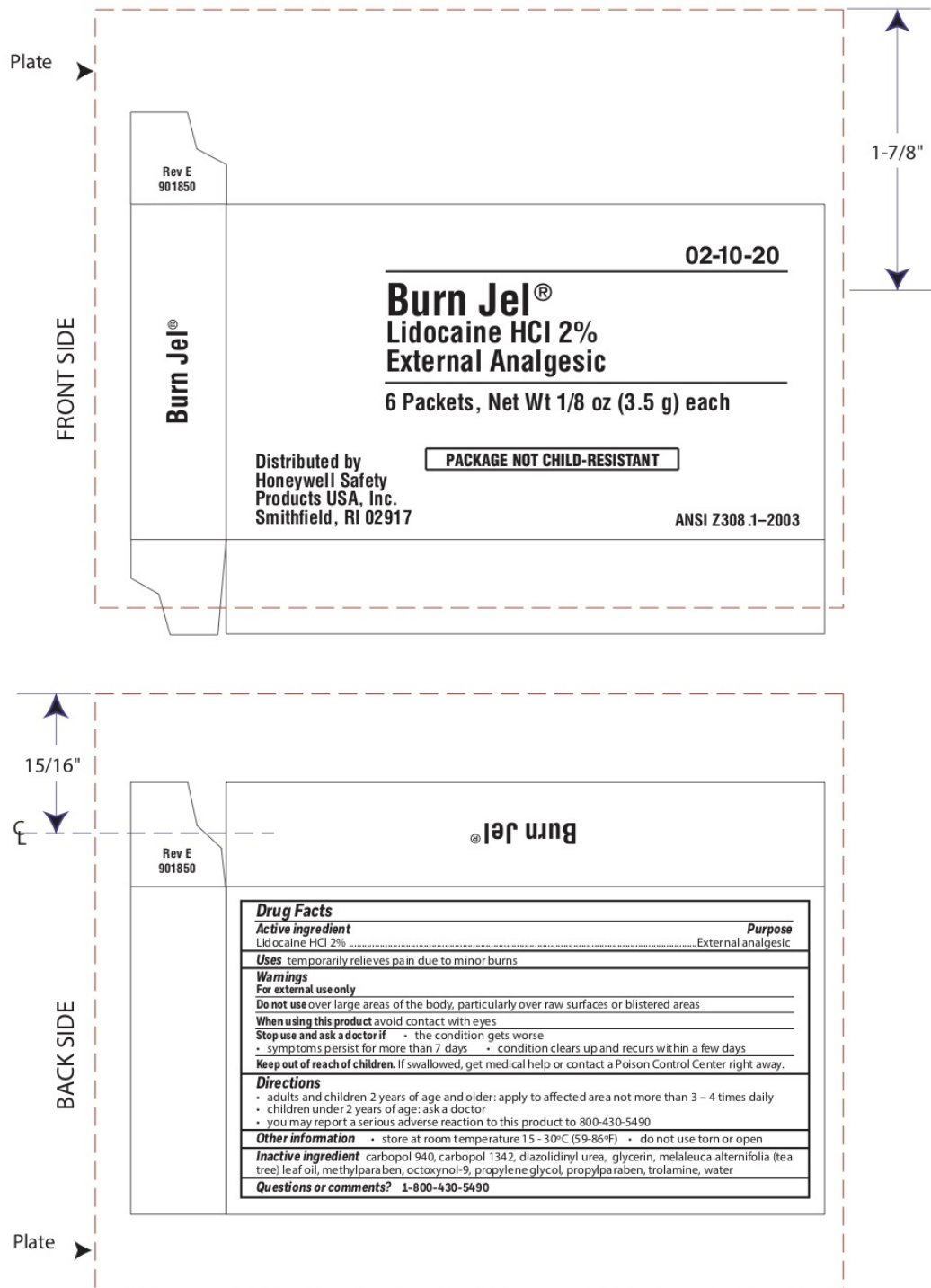
carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water

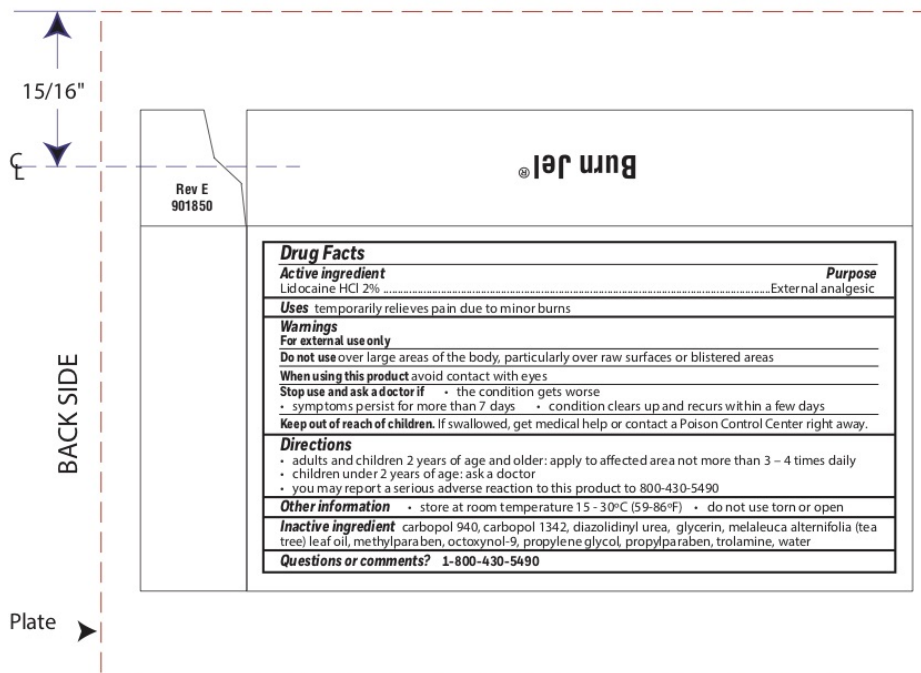
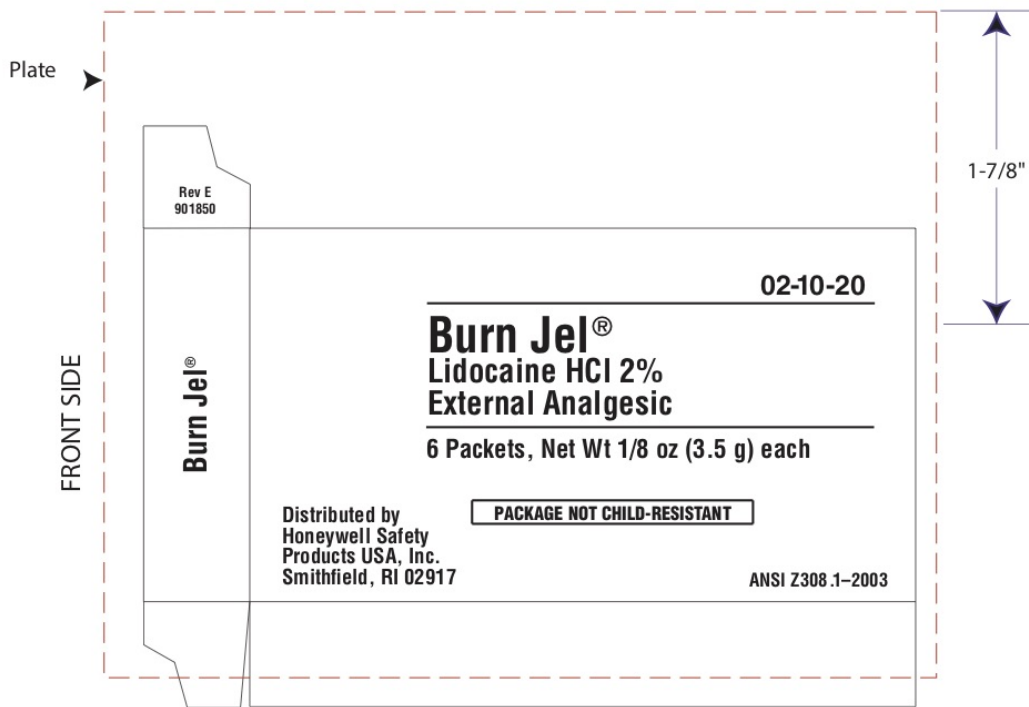
Questions

1-800-430-5490

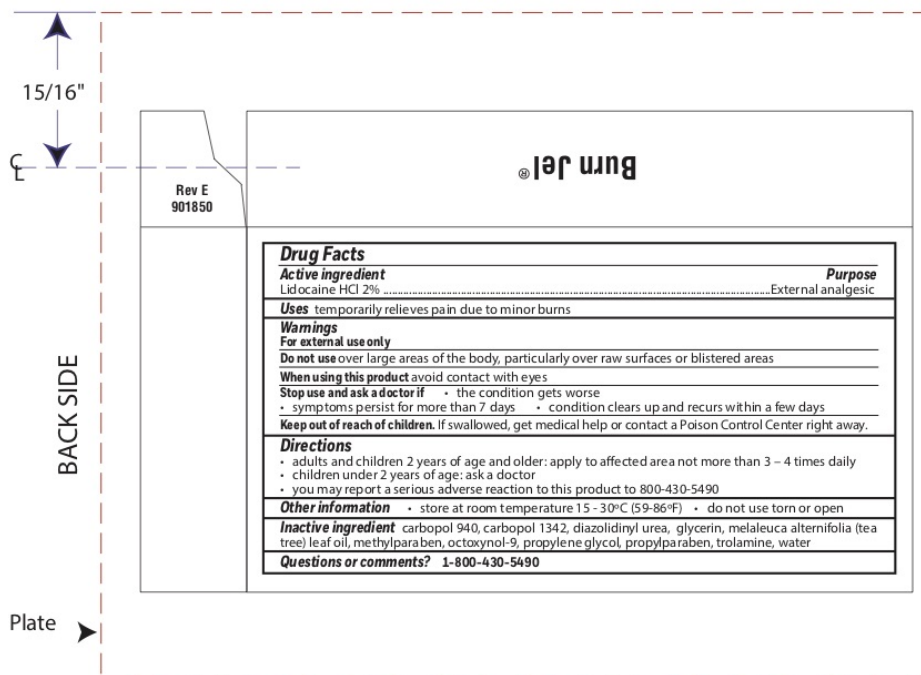
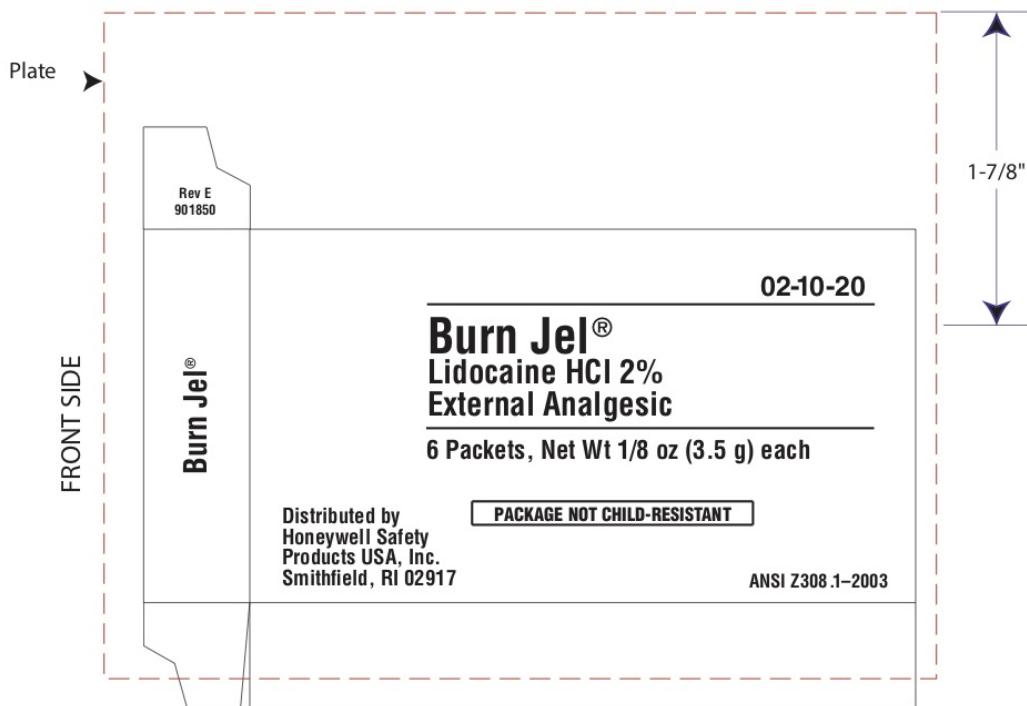
Principal Display Panel

796353 Rev. E Unit Carton Printing Plate for "B" size carton.





796353 Rev. E Unit Carton Printing Plate for "B" size carton.



gel for burns gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-0202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0202-34	10 in 1 CARTON	09/18/2018	09/19/2018
1	NDC:0498-0202-00	3.5 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	09/19/2018

NORTH BURN JEL

gel for burns gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-0200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0200-34	10 in 1 CARTON	12/08/2017	09/18/2018
1		3.5 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/08/2017	09/18/2018

BURN JEL gel for burns gel
Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:0498-0203
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)			LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g
Inactive Ingredients				
Ingredient Name				Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)				
GLYCERIN (UNII: PDC6A3C00X)				
TEA TREE OIL (UNII: VIF565UC2G)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
TROLAMINE (UNII: 9O3K93S3TK)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)				
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-34	10 in 1 CARTON	09/19/2018	
1	NDC:0498-0203-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			09/19/2018	

Labeler - Honeywell Safety Products USA, Inc (118768815)

Registrant - Honeywell Safety Products USA, Inc (118768815)