SUNBURNT PLUS PAIN RELIEF- lidocaine hydrochloride gel
Welmedix LLC dba Welmedix Consumer Healthcare

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.

SunBurnt® PLUS Pain Relief Gel

Drug Facts

Active ingredient

Lidocaine hydrochloride 1.0%

Purpose

External analgesic

Uses

Temporarily relieves pain and itching due to:
- sunburn
- minor burns
- insect bites
- minor skin irritations
- minor cuts
- scrapes

Warnings

For external use only

Do not use
- in large quantities, particularly over raw surfaces or blistered areas
- if you have an allergy or hypersensitivity to any ingredients

Ask a doctor before use if
- you have severe sunburn
- you have a rash or broken or compromised skin

When using this product
- avoid contact with eyes

Stop use and ask a doctor if
- condition worsens
- symptoms last more than 7 days or clear up and occur 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
- clean skin and apply to affected area

- adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily
- children under 2 years of age: ask a doctor

Other information

- store at 15-30°C (59-86°F)
- do not use if seal under cap is open or missing

Inactive ingredients

water, ethyl alcohol, echinacea angustifolia extract, calendula officinalis extract, cantharis vesicatoria extract, gelidiella acerosa extract, hypnea musciformis extract, cucumis sativus (cucumber) seed extract, aloe barbadensis leaf juice, panthenol, sodium hyaluronate, carbomer, sodium hydroxide, phenoxyethanol, ethylhexylglycerin

Questions or Comments?

1-888-565-2876 Monday through Friday, 9am-5pm EST

Dist. by: **Welmedix Consumer Healthcare**
Princeton, New Jersey 08540

PRINCIPAL DISPLAY PANEL - 142 g Tube Carton

NEW!

SUN
BURNT®
PLUS
PAIN RELIEF GEL
with **LIDOCAINE HCL 1%**

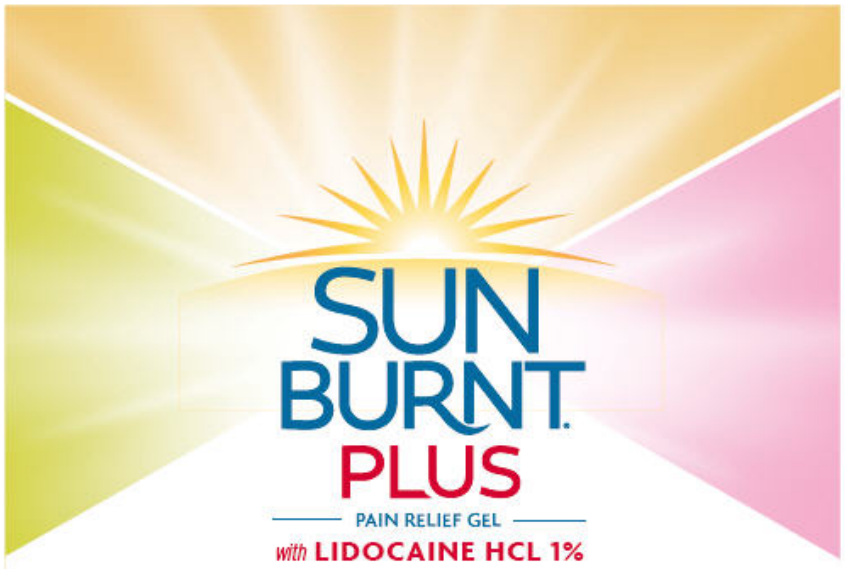
FAST RELIEF FOR
PAIN & ITCH

ULTRA
HYDRATING

NOURISHING
BOTANICALS

NON-STICKY
FORMULA

Net Wt 5 oz (142 g)



SUN BURNT PLUS

PAIN RELIEF GEL

with **LIDOCAINE HCL 1%**

FAST RELIEF FOR PAIN & ITCH

LOVE YOUR SKIN!

NO SULFATES

NO PARABENS

NO PEGS

NO PHTALATES

NO DYES

NO FRAGRANCE

ULTRA HYDRATING

NOURISHING BOTANICALS

NON-STICKY FORMULA

Net Wt 5 oz (142 g)

HYPO-ALLERGENIC

3 24330 24001 2

SUN BURNT PLUS

PAIN RELIEF GEL

with **LIDOCAINE HCL 1%**

Get fast pain & itch relief for sunburn, minor burns, insect bites, minor skin irritations, minor cuts, scrapes and more!

MUCH MORE THAN ALOE®

SunBurnt's non-sticky formula combines fast pain relief with our unique blend of nourishing botanicals

LIDOCAINE

CALENDULA

ECHINACEA

ALGAE EXTRACT

CUCUMBER

ALOE VERA

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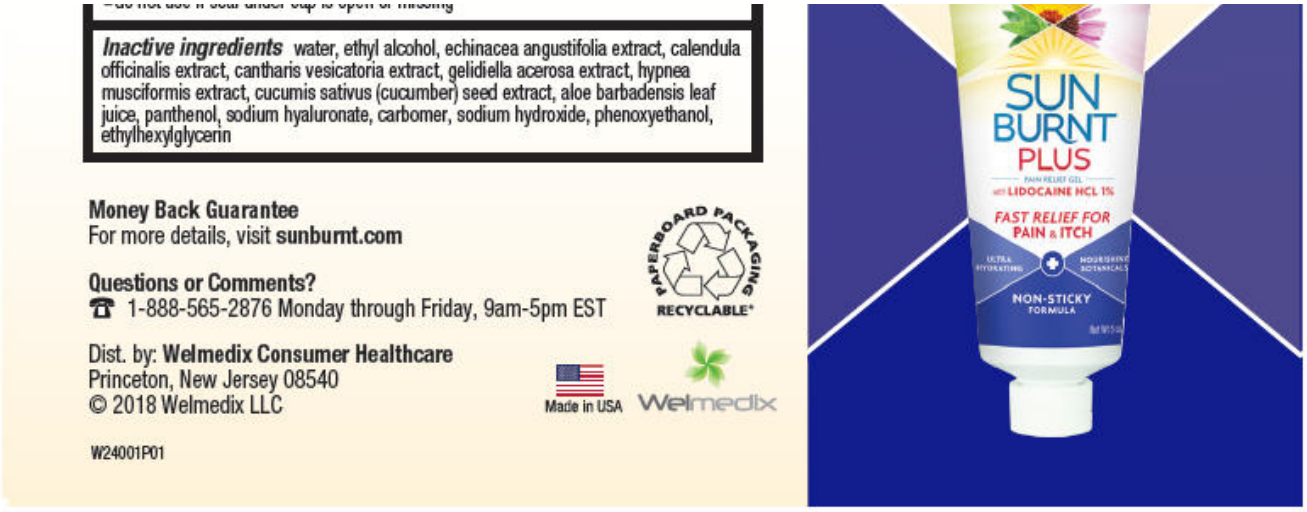

SUNBURNT PLUS PAIN RELIEF

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:24330-240
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8)	
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ)	
LYTTA VESICATORIA (UNII: 3Q034RO3BT)	
GELIDIELLA ACEROSA (UNII: T91K54D6M1)	
HYPNEA MUSCIFORMIS (UNII: W6FF9R1FJV)	
CUCUMBER SEED (UNII: BT3S9L53JK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Panthenol (UNII: WV9CM0O67Z)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
Sodium hydroxide (UNII: 55X04QC32I)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24330-240-01	1 in 1 CARTON	03/15/2018	
1		142 g in 1 TUBE; 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	03/15/2018	

Labeler - Welmedix LLC dba Welmedix Consumer Healthcare (830387812)

Revised: 3/2018 Welmedix LLC dba Welmedix Consumer Healthcare