## BURN RELIEF GEL- lidocaine hydrochloride gel Cross Brands Contract Filling

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.

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#### **Coolest Burn Relief 16oz**

### **Active Ingredients**



Lidocaine Hydrochloride 0.5%

## Purpose



Sea&Ski® Coolest Burn Relief™ soothes and cools burns, scrapes, skin irritations and insect bites. Formulated with Lidocaine HCL to aid in pain and itch relief.







#### Uses



soothes and cools burns, scrapes, skin irritations and insect bites, Formulated with Lidocaine HCL to aid in pain and itch relief.

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Active ingredients

Purpose

Lidocaine Hydrochloride 0.5% Topical Anesthetic **Uses** Temporary relief of pain and litching. Helps to relieve and soothe pain from sunburn, minor burns, skin irritations, scrapes, insect biles.

Warnings For external use only.

Other warnings (wad contact with eyes, Stop use and ask a doctor in contains werene, or if samptons passed for more than 7 days or clear ap and occur spain within a leve days. Pregnancytheased Feeding warning. If pregnant or treast-leading, ask a health care professional before see, Do not see a large spanish, perfocularly over one curiouse or areas with tisters.

Keep out of reach of children. It smallowed, get medical help

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Inactive ingredients acrystes/C10-30 alkyl scryste crossopymer, alcohol denaured, algoe sonact, also barbadensis led juce, subytene glycol, ethylhesylghoerin, F08C Blye No. 1, fragrance, glycerin, menthyl lactate, FEG-40 bydrogenated caster ol, ghencoyethanol, polysorbate 20, FPG-26-busch-26, simmondsia chinerais (jojoba) extract, triethanolamine, water

Questions or comments? Call 855-sea-n-ski (855-732-6754) or visit www.seaNski.com



Manufactured and Distributed by: Cross Brands Contract Filling, LLC 4401 Fortune Place, West Melbourne, FL 32904

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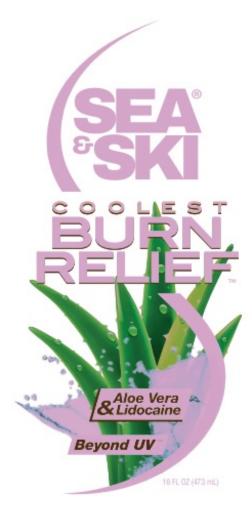


Sea&Skr Coolest Burn Relief soothes and cools burns, scrapes, skin irritations and insect bites. Formulated with Lidocaine HCL to aid in pain and itch relief.



Temporary relief of pain and itching. Helps to relieve and soothe pain from sunburn, minor burns, skin irritations, scrapes, insect bites.

## **Warnings**



For external use only

## **Other Warnings**



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	Fai	

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Sea&Skr<sup>®</sup> Coolest Burn Relief\* soothes and cools burns, scrapes, skin imitations and insect bites. Formulated with Lidocaine HCL to aid in pain and itch relief.



Avoid Contact with eyes.

## Stop use and ask a doctor if:

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.





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Ke	ep out of reach of children. If swatowed, get medical he stast a Poison Control Center right away.
bun imi	<b>OCTIONS</b> Adults and children 2 years or older, apply generously to the draws. Repeat application as often as necessary (see more than four clash) to further codinguish pain. Children under 2 years of age: do not task a doctor.
glyo phe	ctive ingredients acrylstesC10-30 aleyt acrylste polymer, alcohol denstured, algos extract, alee barbedensis leat burglene glycol, strephonylsyboern, FDSC Blue No. 1, fragrance, order, mentifyl jactais, FSG-40 bydrogenated castor oil, cocyethanol, polysochate 20, PSG-26-busch-26, simmondisia resis (jojoba) ediract, triethanolpmine, water
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8	Made in U.S.A.  17013 02161 4  schued and Datinbured by: Brands Contract Filling, LLC
ros	Fortune Place, West Melbourne, FL 32904

## Pregnancy/breast-feeding warning

If pregnant or breast-feeding, as a health care professional before use.

#### Do not use

in large quantity, particularly over raw surfaces or areas with blisters.





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ì	Made in U.S.A.  Made in U.S.A.  Made in U.S.A.  Analysis of the control of the co
	101 Fortune Place, West Melbourne, FL 32904

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.





Sea&Skr<sup>®</sup> Coolest Burn Rellet<sup>®</sup> soothes and cools burns, scrapes, skin imitations and insect bites. Formulated with Lidocaine HCL to aid in pain and itch relief.

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ì	Made in U.S.A.  17013 02161 4  analyzing and Distributed by: cos Brands Contract Fijing, LLC
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### **Directions**

Adults and children 2 years or older: apply generously to the burned area. Repeat application as often as necessary (no more than four times daily) to further extinguish pain. Children under 2 years of age: do not use, ask a doctor





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cross; juice, glycer pheno	tutylene glycol, ethylh in, menthyl lactate, PE	lured, algae ext exylglycerin, FC G-40 hydrogen i 20, PPG-25-b	ract, aloe barbadensis leaf D&C Blue No. 1, fragrance, ated castor oil, uteth-95, simmondsia
	tions or comment 55-sea-n-ski (855		r visit www.seaNski.com
8	47013-028	161 4	Made in U.S.A.
	ctured and Distributed		

## **Inactive ingredients**

acrylates/C1030 alkyl acrylate crosspolymer, alcohol denatured, algae extract, aloe barbadensis leaf juice, butylene glycol, ehtylhexylglycerin, FD&C Blue No. 1, fragrance, glycerin, menthyl lactate, PEG-40 hydrogenated castor oil, phenoxyethanol, polysorbate 20, PPG-26-butheth-26, simmondsia chinensis (jojoba) extract, triethanolamine, water.





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### **BURN RELIEF GEL**

lidocaine hydrochloride gel

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Produc	T INTO	rmation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:73440-2161

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength	
OCAINE HYDROCHLORIDE (LINII: \/130077./1A\) (LIDOCAINE -	LIDOCAINE HYDROCHLORIDE	2 4123 a	

UNII:98PI200987)

ANH

LIDOCAINE HYDROCHLORIDE 2.4123 g in 482.46 g

### **Inactive Ingredients**

Ingredient Name	Strength

**WATER** (UNII: 059QF0KO0R) 436.1 g in 482.46 g

#### **Product Characteristics**

- Todalica Cilia dictorio di Colore				
Color	blue (Clear)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

## **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73440- 2161-1	482.46 g in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2021	

## **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part348	02/08/2021	

## Labeler - Cross Brands Contract Filling (117871824)

# Establishment

Name	Address	ID/FEI		<b>Business Operations</b>	
Cross Brands Contract Filling		117971924	label(73440-2161)	manufacture(73/40-2161)	nack(73/4/0-2161)

Cross Brands Contract Filling 117871824 | label(73440-2161) , manufacture(73440-2161) , pack(73440-2161)