

# 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.*

### Cooler Burn Relief 16oz

### Active Ingredients



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

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Lidocaine Hydrochloride 0.5%	Topical Anesthetic
<b>Uses</b> Temporary relief of pain and itching. Helps to relieve and soothe pain from sunburn, minor burns, skin irritations, scrapes, insect bites.	
<b>Warnings</b> For external use only.	
<b>Other warnings</b> 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. <b>Pregnancy/breast-feeding warning:</b> If pregnant or breast-feeding, ask a health care professional before use. Do not use in large quantity, particularly over raw surfaces or areas with blisters.	
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<b>Inactive ingredients</b> acrylates/C10-30 alkyl acrylate crosspolymer, alcohol denatured, algae extract, aloe barbadensis leaf juice, butylene glycol, ethylhexylglycerin, FD&C Blue No. 1, fragrance, glycerin, menthyl lactate, PEG-40 hydrogenated castor oil, phenoxethanol, polysorbate 20, PPG-26-buteth-26, simmondsia chinensis (jojoba) extract, triethanolamine, water	
<b>Questions or comments?</b> Call 855-sea-n-ski (855-732-6754) or visit <a href="http://www.seaandski.com">www.seaandski.com</a>	



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Topical Anesthetic

Uses



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## Pregnancy/breast-feeding warning

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# COOLEST BURN RELIEF™



**Aloe Vera & Lidocaine**

**Beyond UV™**

16 FL OZ (473 mL)



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# BURN RELIEF GEL

lidocaine hydrochloride gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73440-2161
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.4123 g in 482.46 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	436.1 g in 482.46 g

## Product Characteristics

<b>Color</b>	blue (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

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

## Marketing Information

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

**Labeler** - Cross Brands Contract Filling (117871824)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Cross Brands Contract Filling		117871824	label(73440-2161) , manufacture(73440-2161) , pack(73440-2161)

