LEADER AFTER SUN COOLING- lidocaine hydrochloride gel
CARDINAL HEALTH, 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.

Leader After Sun Cooling Gel

Active Ingredient

Lidocaine hydrochloride 0.5%

Purpose

External Analgesic

Uses

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

Warnings
- **For External Use Only**

Do not use

in large quantities, particularly over raw surfaces or blistered areas.

When using this product
- Avoid contact with eyes. If contact occurs, rinse with water to remove.

Stop use and ask a doctor if
- condition gets worse
- symptoms last more than 7 days
- symptoms clear up and occur again in 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

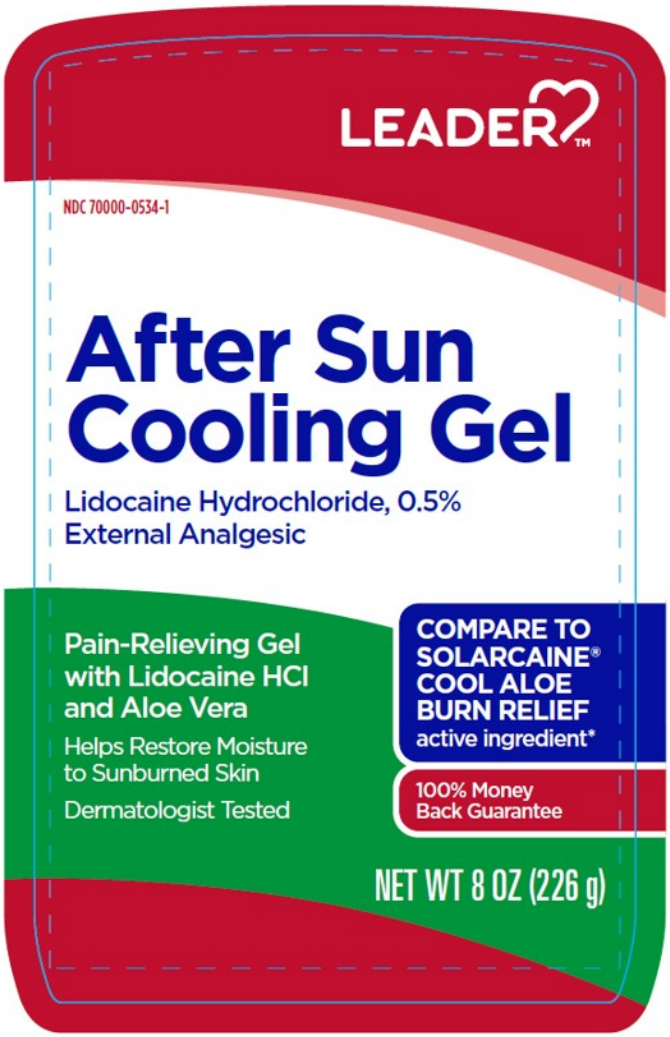
Other information

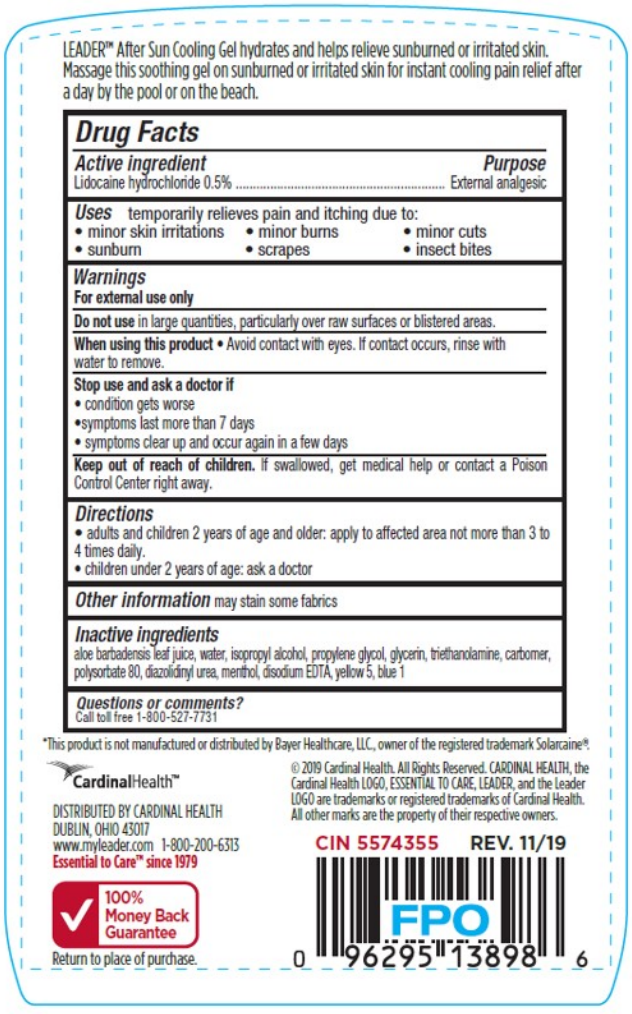
may stain some fabrics

Inactive Ingredients

aloe barbadensis leaf juice, water, isopropyl alcohol, propylene glycol, glycerin, triethanolamine, carbomer, polysorbate 80, diazolidinyl urea, menthol, disodium EDTA, yellow 5, blue 1

Label





LEADER AFTER SUN COOLING

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0534
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
MENTHOL (UNII: L7T10EIP3A)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70000-0534-1	226 g in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/04/2019	

Labeler - CARDINAL HEALTH, INC. (063997360)