

SCLERACARE LIDOCAINE HCL- lidocaine hydrochloride gel

ScleraCare, LLC

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.

ScleraCare Lidocaine HCL 3% Gel

Drug Facts

Active Ingredient:

Lidocaine hydrochloride 3.00%

Purpose

Topical Anesthetic

Uses:

- For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations.

Warnings:

- **For external use only** not intended for ingestion.

When using this product

- Avoid contact with eyes

Do not use

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

Stop use and ask a doctor if

symptoms persist for more than seven days.

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- If pregnant or breast feeding, contact physician prior to use.

Directions:

- Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.
- Children under two-years of age: consult a physician.

Inactive Ingredients:

a-Bisabolol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf (Aloe

Vera Gel) Juice, Aqua (Deionized Water), Butylene Glycol, Cucumis Sativus (Cucumber) Fruit Extract, Ethylhexylglycerin, Opuntia Vulgaris (Prickly Pear) Extract, Persea gratissima (Avocado) Oil, Phenoxyethanol, Polysorbate-20, Sodium Alginate, Squalane, Triethanolamine.


Other Information:

- Store at room temperature

Question?

337-526-6744 (M-F) (9-5pm EST)

Package Labeling:



Lidocaine HCL 3% Gel
Topical Anesthetic

Drug Facts

Active Ingredient:	Purpose
Lidocaine hydrochloride 3.00%.....	Topical Anesthetic
Uses:	
• For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations.	
Warnings:	
• For external use only not intended for ingestion.	
When using this product • Avoid contact with eyes	
Do not use • in large quantities, particularly over raw surfaces or blistered areas	
Stop use and ask a doctor if symptoms persist for more than seven days.	
<ul style="list-style-type: none"> • Keep out of reach of children. • If swallowed, get medical help or contact a Poison Control Center right away. • Do not apply to wounds or damaged skin. • Do not bandage tightly. • If pregnant or breast feeding, contact physician prior to use. 	
Directions:	
• Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.	
• Children under two-years of age: consult a physician.	
Inactive Ingredients:	
a-Bisabolol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Butylene Glycol, Cucumis Sativus (Cucumber) Fruit Extract, Ethylhexylglycerin, Opuntia Vulgaris (Prickly Pear) Extract, Persea gratissima (Avocado) Oil, Phenoxyethanol, Polysorbate-20, Sodium Alginate, Squalane, Triethanolamine.	
Other Information:	
• Store at room temperature	
Question?	
337-526-6744 (M-F) (9-5pm EST)	

NET WT. 6oz (177ml)

Distributed by:
ScleraCare, LLC Lake Charles, LA., 70605
337-526-6744

SCLERACARE LIDOCAINE HCL
lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73698-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CUCUMBER (UNII: YY7C30VXJT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SQUALANE (UNII: GW89575KF9)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73698-106-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/10/2020	

Labeler - ScleraCare, LLC (114220391)