

AVADERM- lidocaine hcl, menthol cream
MAS Management Group 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.

Active Ingredient:

Lidocaine HCL	4.00%	Topical Analgesic
Menthol	1.00%	Topical Analgesic

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

Keep out of reach of children. If swallowed, consult physician.

AvaDerm

(Lidocaine - Menthol)

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.

Warnings:

- Avoid contact with eyes.
- If symptoms persist for more than seven days, discontinue use and consult physician.
- Do not use in large quantities, particularly over raw surfaces or blistered areas.
- Do not bandage tightly.
- If pregnant or breast feeding, contact physician prior to use.

Other Ingredients:

aqua (deionized water), arnica montana flower extract, C13-14 isoparaffin, cetearyl alcohol, chondroitin sulfate, emu oil, ethylhexylglycerin, glucosamine sulfate, glycerin, glyceryl stearate, laureth-7, methylsulfonylmethane (MSM), PEG-100 stearate, phenoxyethanol, polyacrylamide, propylene glycol, stearic acid, triethanolamine, urea.

Drug Facts:		
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Directions:		
<ul style="list-style-type: none"> • 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. 		
Other Ingredients:		
Aqua (Deionized Water), Arnica Montana Flower Extract, C13-14 Isoparaffin, Cetearyl Alcohol, Chondroitin Sulfate, Emu Oil, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Glyceryl Stearate, Laureth-7, Methylsulfonylethane (MSM), PEG-100 Stearate, Phenoxethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine, Urea.		

AvaDERM

(Lidocaine - Menthol)

Distributed by:
 MAS Pharma
 Encino, CA 91436
 Made in USA
 Patent pending
 Questions or comments?
 Call 1-800-768-3518 or email info@maspharma.net



120 gm (4 fl oz)

AVADERM			
lidocaine hcl, menthol cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69677-020
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
Inactive Ingredients			
	Ingredient Name		Strength
	WATER (UNII: 059QF0KO0R)		
	ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)		
	C13-14 ISOPARAFFIN (UNII: E4F12ROE70)		
	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
	CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)		

EMU OIL (UNII: 344821WD61)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
LAURETH-7 (UNII: Z95S6G8201)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
UREA (UNII: 8W8T17847W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69677-020-01	120 g in 1 PACKAGE; 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	07/08/2015	

Labeler - MAS Management Group Inc. (079363782)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, Inc.		969241041	manufacture(69677-020)

Revised: 7/2015

MAS Management Group Inc.