

AVADERM- lidocaine hcl, menthol cream
Pure Source, LLC

AvaDerm

☐ *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:		
Active ingredient:		
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Menthol	1.00%	Topical Analgesic
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Warnings:		
<ul style="list-style-type: none"> • Avoid contact with eyes. • If symptoms persist for more than seven days, discontinue use and consult physician. • Keep out of reach of children. If swallowed, 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. 		
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, Phenoxyethanol, 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:65121-300
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:65121-300-01	120 g in 1 PACKAGE; Type 0: Not a Combination Product	06/10/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/10/2015	

Labeler - Pure Source, LLC (080354456)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(65121-300)

Revised: 11/2023

Pure Source, LLC