PREDATOR- lidocaine hcl cream
Sambria Pharmaceuticals, 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.

Predator

Information for Patients

This product is not to be administered orally (mouth) or in the ocular (eye) area.

If used improperly by oral administration the patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, any device (including hands and fingers) used to administer this product topically should be cleaned well before possible contact with eyes, intra-nasaly or mouth.

active ingredients

lidocaine HCL 4%

Other ingredients

Aqua, Amica Montana Extract, C13-14 Isoparafin, Chondrotin Sulfate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth 7, Melaleuca Alternifoil (Tea Tree) oil, Methylsulfonylmethana (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine

This product should be kept out of the reach of children uner twelve (12) years of age.

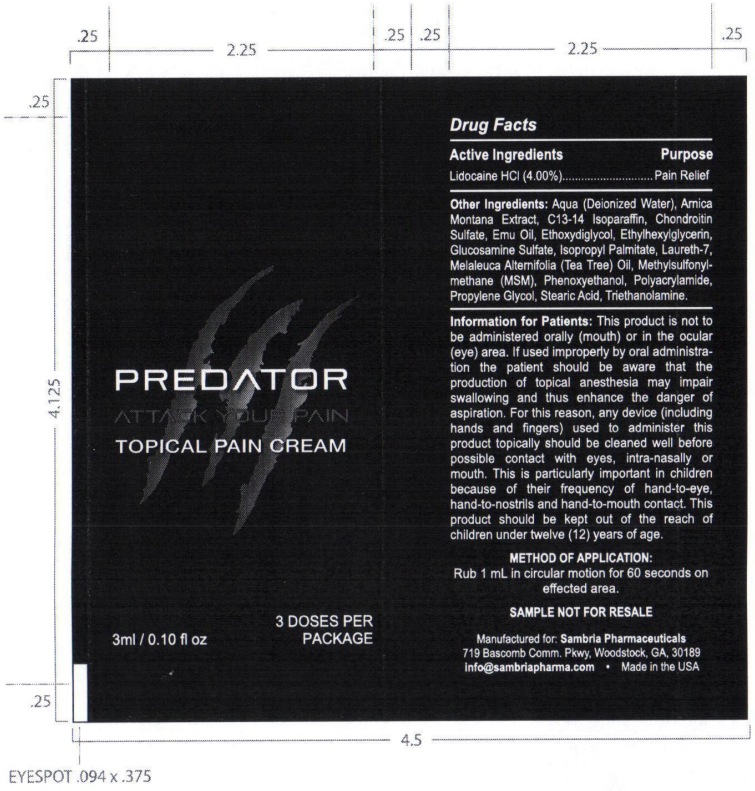
Pain relief

Method of Application

Rub 1ml in circular motion for 6 0seconds on effected area.

Rub 1ml in cicular motion for 60 seconds on effected area.

PREDATOR



21st Century LABELS
11840 Miramar Parkway
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Document Info

File: Predator 3mL
Size: 4.5 X 4.125
21C#: PUR 1060
Date: 01-25-13
PROOF: 2

Colors

black	485	000	000	000
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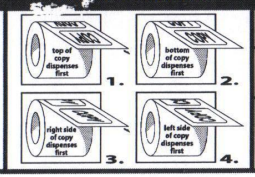
Label Position Chart



Customer Approval

Please mark all changes clearly and legibly on this proof and E-mail, fax or deliver to 21st Century Labels

Purchase Order#	Quantity
Signature	Date

NOTE: COLOR PROOFS ARE PROVIDED ONLY AS A VISUAL REFERENCE TO THE FINAL PRINTED PIECE. THE COLORS SHOWN ARE ONLY REPRESENTATIONAL, AND ARE NOT INTENDED TO MATCH ACTUAL PRESS COLOR.

lidocaine hcl cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	400 mg in 1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
EMU OIL (UNII: 344821WD61)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LAURETH-7 (UNII: Z95S6G8201)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54723-150-03	400 mg in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/11/2013	

Labeler - Sambria Pharmaceuticals, LLC (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(54723-150)

Revised: 2/2013

Sambria Pharmaceuticals, LLC