PREDATOR- lidocaine hydrochloride 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

For external use only

Avoid contact with eyes

If symptoms persist for more than seven days, or clear up and occur again within a few days, discontinue use and consult physician

If redness, irritation, swelling, pain or ot5her symptoms increase, discontinue use and consult physician

If swallowed consult physician.

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

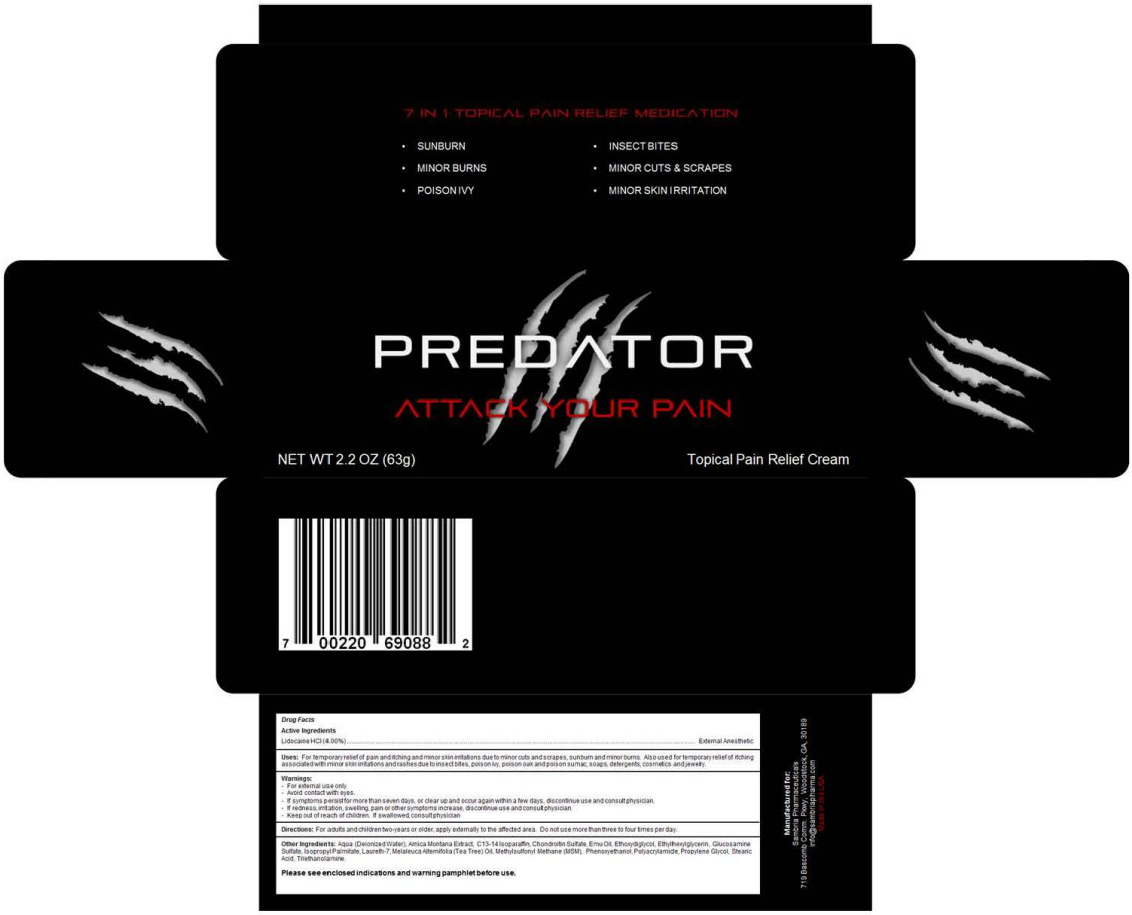
Keep out of reach of children

External anesthetic

For adults and children two years or older, apply externally to the affected area. Do not use more than three to four times per day.

Uses

For temporary relief of pain and itching and minor skin irratations due to minor cuts and scrapes, sunburn and minor burns. Also used for temporary relief of itching associated with minor skin irritations and rashes due to insect bites, poison ivy, poison oak and poison sumac, soaps, detergetns, cosmetics and jewelry.



PREDATOR

lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54723-101
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:54723-101-02	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(54723-101)

Revised: 3/2013 Sambria Pharmaceuticals, LLC