

ARTE MAXIMUM STRENGTH NUMBING CREAM- lidocaine hydrochloride cream
Sambria Pharmaceuticals, LLC

Drug Facts

Active ingredient

Lidocaine HCL 4.0% w/w

Purpose

External Analgesic

Uses

For temporary relief of pain and itching.

Warnings

For external use only.

Do not use on wounds or damaged skin, in large quantities, or if you are allergic to any ingredients of this product.

When using this product use only as directed. Avoid contact with the eyes, rashes, or mucous membranes.

Stop use and ask doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children and pets

If swallowed get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and over: Clean and dry affected area, apply to affected area not more than 3 to 4 times daily.

Children 12 years of age or younger: ask a doctor.

Other information

Protect this product from excessive heat and direct sun.

Inactive ingredients

Aqua (Deionized Water), Arnica Montana Flower Extract, C13-14 Isoparaffin, Chondroitin Sulfate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine

Product label

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ARTE MAXIMUM STRENGTH NUMBING CREAM			
lidocaine hydrochloride cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-024
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
EMU OIL (UNII: 344821WD61)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LAURETH-7 (UNII: Z95S6G8201)	
TEA TREE OIL (UNII: VIF565UC2G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: 56C14G5FWO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-024-01	30 g in 1 TUBE; Type 0: Not a Combination Product	02/07/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/07/2025	

Labeler - Sambria Pharmaceuticals, LLC (078676259)

Establishment

Name	Address	ID/FEI	Business Operations
Southeast Holdings Corp		080504027	manufacture(54723-024)

