SMART NUMB LIDOCAINE CREAM- lidocaine cream
M.J. Winston International, Ltd.

WARNINGS

For external use only.

Stop use and ask a doctor if the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop. If pregnant or breast-feeding, ask a health professional before use.

In case of accidental overdose, contact a doctor or Poison Control Center immediately. Keep out of reach of children.

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Active Ingredients

Lidocaine 5% local anesthetic

DRUG FACTS

Active Ingredients	Purpose
Lidocaine 5%	Local Anesthetic

Use

For the temporary relief of pain, burning, and soreness associated with anorectal discomfort or inflammation.

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Directions

Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product. For products for external use only. Apply up to 6 times a day. Children under 12 years of age: consult a doctor.

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Inactive Ingredients

Aacrylates, Allantoin, Arnice Montana Flower Extract, Deionized Water, Dimethyl Isosorbide, Emu Oil, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Polydecene, Menthol, Phenoxythanol, Propylene Glycol, Sodium Polyacrylate, Tetrasodium Edta, Tocopheryl Acetate, Trideceth-6

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Other Information

Store at 59F to 86F (15C to 30C). Keep away from direct sunlight.

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Questions or concerns?

Contact info@smartmed.us or 714-582-2715.

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SMART NUMB LIDOCAINE CREAM

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76092-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
MENTHOL (UNII: L7T10EIP3A)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
HYDROGENATED POLYDECENE (1500 CST) (UNII: 4YI0729529)	
WATER (UNII: 059QF0KO0R)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EMU OIL (UNII: 344821WD61)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76092-201-02	57 g in 1 JAR; Type 0: Not a Combination Product	03/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	03/15/2024	

Labeler - M.J. Winston International, Ltd. (144927378)

Establishment

Name	Address	ID/FEI	Business Operations
M.J. Winston International, Ltd.		144927378	label(76092-201)

Revised: 2/2024

M.J. Winston International, Ltd.