

NUMB NUTS - lidocaine cream
Miss Smarty Pants Enterprises, Inc.

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.

Numb Nuts The Manscaper's Pain Relieving Cream

DRUG FACTS

For Pain Relieving Cream

Active Ingredient	Purpose
Lidocaine 4%	Topical Analgesic

purpose
topical analgesic

Uses

for the temporary relief of pain associated with minor skin irritations due to groin area hair removal.

WARNINGS

For external use only.

Avoid contact with the eyes

Do not use

with other creams or medications

in large quantities, particularly over raw surfaces or blistered areas

if you have had a severe allergic reaction (e.g. severe rash, hives, difficulty breathing, dizziness) to any anesthetic medicine

if there are signs of infection or tissue damage in the affected area.

Ask a doctor before use if you have heart or neurological conditions.

Stop use and ask a doctor if

you develop a persistent rash

side effects occur

condition worsens or symptoms persist for more than 7 days.

Keep out of reach of children. If swallowed get medical help or contact poison control center right away.

Directions

For adult use only. Apply a small amount of cream to the groin area between 15 and 30 minutes prior to groin area hair removal. Do not rub in. A thin layer of cream should be visible on the skin.

Other information

Cream is packaged with an imprinted wrap around neck of tube

do not use if carton is damaged or open, or if imprinted wrap around neck of tube is damaged or missing.

See crimp of tube for lot number and expiration date

Store at room temperature (68 to 77 degrees F, 20 to 25 degrees C)

Aloe Barbadensis Leaf Juice, Caprylyl Glycol, Cetyl Alcohol, Hexylene Glycol, Phenoxyethanol, Potassium Sorbate, Simmondsia Chinesis (Jojoba) Seed Oil, Sodium Polyacrylate, Stearic Acid, Water

Numb Nuts

The Manscaper's Pain Relieving Cream

Package contents:

1 Tube [0.5 oz (14.2 g)] of pain relieving cream

for more information visit

www.numbnuts.com

NUMB NUTS

The Manscapers Pain Relieving Cream

Doctor Formulated

Pain Relieving Cream with Aloe

NUMB NUTS Pin Relieving Cream with Aloe

The Manscaper's Pain Relieving Cream

Net Wt 0.5 oz (14.2 g)

Created and manufactured for

Miss Smarty Pants Enterprises, Inc.

PO Box 10446, Beverly Hills, CA 90213

Packaging and Pain Relieving Cream-Made in the USA

Numb Nuts Pain Relieving Cream with aloe

The manscapers pain relieving cream

Net Wt 0.5 oz (14.2g)

4% Lidocaine

Do Not Use if imprinted wrap around neck of tube is damaged or missing.

Created and manufactured for Miss Smarty Pants Enterprises, Inc.

PO Box 10446 Beverly Hills, CA 90213

Pain Relieving Cream-Made in USA

This unit is packaged in an outer container. Please see outer container for drug facts information.

See crimp of tube for lot number and expiration date.

Store at room temperature (8 to 77 degrees F, 20 to 25 degrees C).



Drug Facts

For Pain Relieving Cream

Active Ingredient

Lidocaine 4%..... Topical Analgesic

Purpose

Uses

- For the temporary relief of pain associated with minor skin irritations due to groin area hair removal.

Warnings

For external use only.

Avoid contact with the eyes.

Do not use

- with other creams or medications.
- in large quantities, particularly over raw surfaces or blistered areas.
- if you have had a severe allergic reaction (e.g. severe rash, hives, difficulty breathing, dizziness) to any anesthetic medicine.
- if there are signs of infection or tissue damage in the affected area.

Ask a doctor before use if you have heart or neurological conditions.

Stop use and ask a doctor if

- you develop a persistent rash.
- side effects occur.
- condition worsens, or symptoms persist for more than 7 days.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Directions

For adult use only. Apply a small amount of cream to the groin area between 15 and 30 minutes prior to groin area hair removal. Do not rub in. A thin layer of cream should be visible on skin.

Other Information

- Tube contains 2 – 3 applications.
- Cream is packaged with an imprinted wrap around neck of tube.
- Do not use if carton is damaged or open, or if imprinted wrap around neck of tube is damaged or missing.
- See crimp of tube for lot number and expiration date.
- Store at room temperature (68 to 77°F, 20 to 25°C).

Inactive Ingredients

Aloe Barbadosensis Leaf Juice, Benzophenone-4, Blue 1, Caprylyl Glycol, Cetyl Alcohol, Dimethyl Sulfoxide, Hexylene Glycol, Phenoxyethanol, Potassium Sorbate, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Polyacrylate, Stearic Acid, Water.



The Manscaper's
Pain Relieving Cream

Package contents:

- 1 Tube [0.5 oz.(14.2g)]
of pain relieving cream

For more information visit
www.numbnuts.com



NUMB NUTS

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48095-390
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

JOJOBA OIL (UNII: 724GKU717M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0K00R)	
SULISO BENZONE (UNII: 1W6L629B4K)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48095-390-01	1 in 1 BOX		
1		14.2 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	06/10/2010	

Labeler - Miss Smarty Pants Enterprises, Inc. (942928669)

Registrant - Miss Smarty Pants Enterprises, Inc. (942928669)

Establishment

Name	Address	ID/FEI	Business Operations
Miss Smarty Pants Enterprises, Inc.		942928669	manufacture

Revised: 8/2010

Miss Smarty Pants Enterprises, Inc.