

LIDOCARE 03- 4% lidocaine patch
NFI, 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.

Lidocaine Back Patch

Active Ingredients

Lidocaine 4%

Purpose

Topical anesthetic

Use

For the temporary relief of pain.

Warnings

For external use only.

Do not use if pouch is damaged or opened. Do not use

- on large areas of the body or on cut, irritated skin
- on open wounds or sensitive skin
- for more than one week without consulting a doctor
- **do not use if you are allergic to lidocaine or any of the inactive ingredients listed below.**

When using this product

- use only as directed. Read and follow all directions and warnings on this package.
- do not allow contact with the eyes
- do not bandage or apply local heat (such as heating pads) to the area of use
- **do not reuse patch.**

Stop use and ask doctor if

- condition worsens
- rash, itching or skin irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast feeding,

ask a health professional before use.

Keep out of reach of children and pets.

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

Directions

Adults and children over 12 years of age: Apply patch to affected area every 8 to 12 hours.

Children 12 years or younger: Consult a physician before use.

Instructions for Use

- clean and dry affected area
- cut open pouch and remove the patch
- remove clear protective liner from the patch
- apply to affected area no more than three (3) times per day
- leave in place for up to 8 but no more than 12 hours
- wash hands thoroughly after applying or removing patch
- some individuals may not experience pain relief until several minutes or hours after applying a patch
- do not use other local anesthetic products in addition to Lidocare.

Storage Information

- protect from freezing or excessive heat
- store at 68°-77°F (20°-25°C).

Inactive Ingredients

Crospovidone, menthoxypropanediol, non-woven backing fabric, polyester film, non-latex rubber based adhesive, vanillyl butyl ether.

PRINCIPAL DISPLAY PANEL - 3 Patch Carton Label

FROM THE MAKERS OF BLUE-EMU®

Lidocare™
4% LIDOCAINE

**PAIN RELIEF
PATCH**
BACK/SHOULDER

PATENT PENDING
PRESSURE ADHESIVE
PATCH
PATCH SIZE

2.5" x 6"

MADE IN
THE USA

**ULTRA-FLEXIBLE
ODOR-FREE**
FOR THE TEMPORARY RELIEF OF PAIN

3 PATCHES
1 PATCH PER POUCH

**DISTRIBUTED BY:
NFI CONSUMER PRODUCTS
501 Fifth Street
Bristol, TN 37620
Toll Free: 800-432-9334
WWW.LIDOCARE.COM**



LIDOCARE 03

4% lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69993-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 2S7830E561)	
3-(L-MENTHOXY)-2-METHYLPROPANE-1,2-DIOL (UNII: 649M1Y2P72)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69993-400-03	3 in 1 CARTON	05/01/2016	
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2016	

Labeler - NFI, LLC (121681919)

Establishment

Name	Address	ID/FEI	Business Operations
ProSolus, Inc.		969793079	MANUFACTURE(69993-400)