

BIOFREEZE ULTRAFLEX- lidocaine patch
RB Health (US) LLC

Biofreeze Ultraflex

Active ingredient:

Lidocaine 4%

Purpose:

Pain Relieving Patch

Uses

Uses

For the temporary relief of pain

Warnings

For external use only.

Do not use

- more than 1 patch on your body at a time or with other topical anesthetics at the same time
- on wounds, damaged skin, rashes, or swollen skin
- with a heating pad or apply local heat to the area of use
- in large quantities, particularly over raw surfaces or blistered areas

When using this product

- use only as directed
- do not bandage tightly
- avoid contact with the eyes or on mucous membranes
- dispose of used patch in manner that always keeps product away from children and pets.

Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and ask a doctor if

- the condition for which this preparation is used persists or if a rash, redness or irritation develops
- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within few days
- you experience pain, swelling or blistering of the skin

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 a Poison Control Center right away.

Uses

For the temporary relief of pain

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 older: Clean and dry affected area, cut open pouch

and remove patch from protective film by first peeling back center film. Apply exposed patch

to affected area. Carefully remove remaining film while pressing the patch to skin and leave in

place for up to 8 hours. (see images on carton)

□ use 1 patch at a time and not more than 3 to 4 times daily

□ children under 12 years of age: consult a physician

□ wash hands after use with cool water

Other information

□ store at 20-25°C (68-77°F)

□ store in a cool dry place away from direct sunlight

Inactive ingredients:

Butylated Hydroxytoluene, Glyceryl Hydrogenated Rosinate, Mineral Oil, Polyisobutylene, Styrene/Isoprene/Styrene Block Copolymer

Questions or comments? 1-866-682-4639

CUT OPEN HERE

CUT OPEN HERE



NDC 59316-899-07

BIOFREEZE[®]
BLOCK THE PAIN*

ULTRAFLEX
LIDOCAINE 4% PAIN RELIEVING PATCH

HOW TO APPLY



1. Peel back center film and apply exposed patch to affected area.



2. Remove one side of film while pressing the patch to skin.



3. Repeat on other side of patch.

LARGE MAXIMUM STRENGTH[†] PATCH

1 PATCH – 5.5 in X 3.9 in (14 cm X 10 cm)

BIOFREEZE ULTRAFLEX LIDOCAINE 4% PATCH

Drug Facts

Active ingredient

Lidocaine 4%

Purpose

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- adults and children 12 years of age and older: Clean and dry affected area, cut open pouch and remove patch from protective film by first peeling back center film. Apply exposed patch to affected area. Carefully remove remaining film while pressing the patch to skin and leave in place for up to 8 hours. (see illustration)
- use 1 patch at a time and not more than 3 to 4 times daily
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Other information

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Inactive ingredients

Butylated Hydroxytoluene, Glyceryl Hydrogenated Rosinate, Mineral Oil, Polyisobutylene, Styrene/Isoprene/Styrene Block Copolymer

Questions or comments? 1-866-682-4639

Methemoglobinemia has been reported following the use of lidocaine on extremely rare occasions. Stop use and ask your doctor if you have or are suspected to have methemoglobinemia.

Dist. by: RB Health (US), Parsippany, NJ 07054-0224

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Made in Japan

*For the temporary relief of pain

†Available without a prescription

Does not contain NSAIDs,

Ibuprofen, Aspirin or Salicylates

www.biofreeze.com

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EXP.:

LOT:



BIOFREEZE®

BLOCK THE PAIN®



APPLY FOR UP TO
8
HOURS

NDC 59316-899-04

BIOFREEZE®

BLOCK THE PAIN®

ULTRAFLEX

LIDOCAINE 4% PAIN RELIEVING PATCH



SUPERIOR
4-WAY
FLEXIBILITY**



SUPERIOR
ADHESION
TO STAY IN PLACE**

4 LARGE MAXIMUM STRENGTH* PATCHES
5.5 in x 3.9 in (14 cm x 10 cm) each

BIOFREEZE®

BLOCK THE PAIN®

PRESS OPEN

ULTRAFLEX

LIDOCAINE 4% PAIN RELIEVING PATCH

HOW TO APPLY THE PATCH

1. Peel back center film and apply exposed patch to affected area.
2. Remove one side of film while pressing the patch to skin.
3. Repeat on other side of patch.

Drug Facts	
Active ingredient Lidocaine 4%	Purpose Pain Relieving Patch
Uses For the temporary relief of pain	
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Other information	
<ul style="list-style-type: none"> store at 20-25°C (68-77°F) store in a cool dry place away from direct sunlight 	
Inactive ingredients Butylated Hydroxytoluene, Glyceryl Hydrogenated Rosinate, Mineral Oil, Polyisobutylene, Styrene/Isoprene/Styrene Block Copolymer	
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Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
©2025 RB Health
Made in Japan
Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate
www.biofreeze.com
*For the temporary relief of pain
** Available without a prescription
†† vs. hydrogel patches
3324000
022725

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BIOFREEZE ULTRAFLEX

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-899
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCEROL ESTER OF HYDROGENATED ROSIN (UNII: XH62RP786N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POLYISOBUTYLENE (55000 MW) (UNII: TQ77WR8A02)	
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (UNII: K7S96QM8DV)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59316-899-04	4 in 1 CARTON	01/15/2025	
1		2 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:59316-899-07	1 in 1 POUCH	01/15/2025	
2		2 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/15/2025	

Labeler - RB Health (US) LLC (081049410)

Revised: 3/2025

RB Health (US) LLC