

BIOFREEZE ULTRAFLEX PLUS- lidocaine, menthol patch
RB Health (US) LLC

Biofreeze Ultraflex

Active ingredient:

Lidocaine 4%

Menthol 1%

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.

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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



BIOFREEZE ULTRAFLEX PLUS

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59316-898
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.01 g in 1 g
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:59316-898-04	4 in 1 CARTON	01/31/2026	
1		2 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:59316-898-07	1 in 1 POUCH	01/31/2026	
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	01/31/2026	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2026

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