

LABOFLEX LIDOCAINE PAIN RELIEVING PATCH- lidocaine 4% patch
Laboflex, Inc.

LABOFLEX Lidocaine Pain Relieving Patch - lidocaine 4%

Active ingredient

Lidocaine 4%

Inactive ingredients

Carboxymethylcellulose sodium, Dihydroxyaluminum aminoacetate, Edetate sodium, Glycerin, Lidocaine, Urea, Methyl paraben, Partially neutralized Sodium Polyacrylate, Polyacrylic acid, Polysorbate 80, Propyl paraben, Propylene glycol, Sodium Polyacrylate, Tartaric acid, Titanium dioxide, Water.

Directions:

Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: do not use, consult a physician.

- clean and dry affected area
- remove the film from the patch and apply to the affected area
- Use 1 patch at a time and not more than 3 to 4 times daily.
- Remove patch from the skin after at most 8 hours application

Keep Out of Reach of Children

Keep Out of Reach of Children. If swallowed, get medical help or contact a Poison Control Center right away.

If Pregnant or Breast Feeding

If pregnant or breast feeding, ask a health professional before use.

Stop Use and Ask a Doctor if

Stop use and ask doctor if:

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Severe burning sensation, redness or irritation develop
- You experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

When Using This Product

When using the product:

- use only as directed.
- do not bandage tightly
- Avoid contact with the eyes, mucous membranes or rashes
- do not apply to open wounds or damaged skin

Do not Use

Do not use:

- On wounds or damaged skin
- With a heantig pad
- If you are allergic to any ingredients of this product

Warning

For external use only

Uses

For the temporary relief of pain

Purpose

Topical anesthetic

Other information

Other Information:

- Do not use if the pouch is opened or damaged
- Tightly reseal the pouch containing unused patches
- Store at room temperature
- Do not freeze

Principal Display Panel



LABOFLEX LIDOCAINE PAIN RELIEVING PATCH

lidocaine 4% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83655-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3COOX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

TARTARIC ACID (UNII: W4888I119H)
UREA (UNII: 8W8T17847W)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)
METHYLPARABEN (UNII: A2I8C7HI9T)
EDETATE SODIUM (UNII: MP1J8420LU)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83655-109-25	5 in 1 BOX	01/10/2025	
1		1 g 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 Drug	M017	01/10/2025	

Labeler - Laboflex, Inc. (128394050)

Registrant - Laboflex, Inc. (128394050)

Establishment

Name	Address	ID/FEI	Business Operations
WOOSHIN LAPACHE d.o.o.		507385209	manufacture(83655-109)

Revised: 12/2024

Laboflex, Inc.