

ACHELON LIDOCAINE PATCH- lidocaine patch 4% patch
Achelon, Inc

Achelon Lidocaine 4% Patch

Active Ingredient

Lidocaine 4%

Purpose

Topical Analgesic

Inactive Ingredients

Propylene Glycol 400

Levulinic Acid

Brij L4 LQ

Isopropyl palmitate

Use

For the temporary relief of pain

Warnings

For external use only

Do not use

- on raw or blistered skin
- on the eyes
- if allergic to lidocaine or any ingredients in the patch
- more than 4 daily
- with a heating pad

When using this product

- use only as directed
- do not inject through any patch material

Stop use and ask a doctor if

If you develop a rash or skin irritation

If pregnant or breastfeeding

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.

Directions**Adults and children 2 years of age or older:**

- Apply the patch to clean, dry skin 60 minutes prior to procedure
- Immediately prior to procedure, remove the center of the patch, leaving ring in place to outline treated area
- Follow usual needle procedure steps
- Remove ring after procedure

Children under 2 years of age:

Consult a doctor prior to use

Box and Drug Facts Panel



ACHELON LIDOCAINE PATCH

lidocaine patch 4% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84209-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	7.54 mg in 60.81 cm2

Inactive Ingredients

Ingredient Name	Strength
LEVULINIC ACID (UNII: RYX5QG61EI)	

ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
ACRYLIC ACID/ETHYLENE COPOLYMER (600 MPA.S) (UNII: 1PEZ3NLY6I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84209-400-03	3 in 1 BOX	03/26/2025	
1		20.27 cm2 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	03/25/2025	

Labeler - Achelon, Inc (080928345)

Registrant - Akron Coating & Adhesives (186569323)

Establishment			
Name	Address	ID/FEI	Business Operations
Akron Coating & Adhesives		186569323	manufacture(84209-400)