# LIDOZEN- lidocaine hydrochloride, menthol patch Village Pharma LLC

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Lidozen Patch

**DRUG FACTS:** 

#### **ACTIVE INGREDIENTS:**

Lidocaine HCL 4.00%

Menthol 1.00%

**Topical Anesthetic** 

External Analgesic

#### **USES:**

For temporary relief of pain

#### **WARNINGS:**

- For external use only.
- Avoid contact with eyes.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

#### Do not use

in large quantities, particularly over raw surfaces or blistered areas.

## If pregnant or breast-feeding,

ask a health professional before use.

## Keep out of reach of children.

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

## **DIRECTIONS (Adults and Children Over 12 Years):**

Clean and dry affected area.

Remove patch from backing and apply to affected area.

Use only one patch at a time, and maximum of four patches / day.

Leave patch on affected area for up to 8 hours.

Do not use patches for longer than five consective days.

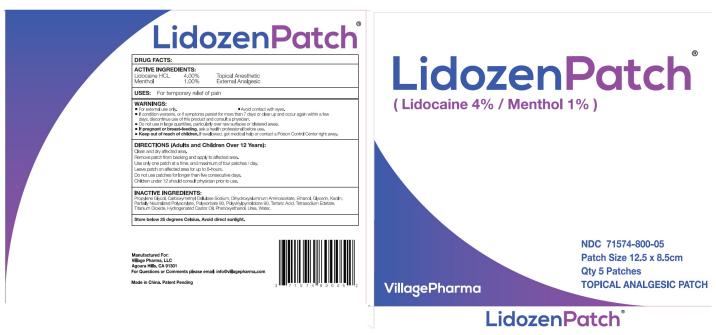
Children under 12 should consult physician prior to use.

### **INACTIVE INGREDIENTS:**

Propylene Glycol, Carboxymethyl Cellulose Sodium, Dihydroxyaluminum Aminoacetate, Ethanol, Glycerin, Kaolin, Partially Neutralized Polyacrylate, Polysorbate 80, Polyvinylpyrrolidone 90, Tartaric Acid, Tetrasodium Edetate, Titanium Dioxide, Hydrogenated Castor Oil, Phenoxyethanol, Urea, Water.

Store below 25 degrees Celsius. Avoid directed sunlight.

## **Package Labeling:**



## **LIDOZEN**

lidocaine hydrochloride, menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71574-800	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g

Inactivo Ingradiants		
Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)		
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)		
ALCOHOL (UNII: 3K9958V90M)		
GLYCERIN (UNII: PDC6A3C0OX)		
KAOLIN (UNII: 24H4NWX5CO)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
TARTARIC ACID (UNII: W48881119H)		
EDETATE SODIUM (UNII: MP1J8420LU)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
UREA (UNII: 8W8T17847W)		
WATER (UNII: 059QF0KO0R)		

P	Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:71574- 800-05	5 in 1 POUCH	05/01/2019			
1		1 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	05/01/2019		

## Labeler - Village Pharma LLC (080749749)

Revised: 11/2023 Village Pharma LLC