

**LIDOZEN- lidocaine hydrochloride, menthol patch**  
**Proficient Rx LP**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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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 consecutive days.

Children under 12 should consult physician prior to use.

## INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf (Aloe Vera Juice) Gel, Aqua (Deionized Water), Arnica Montana Extract, Boswellia Serrata Extract, Camellia Sinensis Leaf (Green Tea) Extract, Carbomer, Ethylhexylglycerin, Glycerin, Isopropyl Myristate, PEG-8, Phenoxyethanol, Polysorbate-80, Sodium Lauryl Sulfate, Triethanolamine, FD&C Blue #1, FD&C Yellow #5

Store below 25 degrees Celsius. Avoid direct sunlight.

## Package Labeling:

**LidozenPatch 4%/ 1%**  
**#30 Patch**

Each patch contains: Lidocaine HCl 4.00% Topical Anesthetic / Menthol 1.00% External Analgesic

See Box

Product ID: RL091730

Mfr. For: Village Pharma, LLC Agoura Hills, CA 91301 Made in China.

Store below 25 degrees Celsius. Avoid direct sunlight. Keep medication out of the reach of children

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

## LIDOZEN

lidocaine hydrochloride, menthol patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-917(NDC:71574-400)
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	40 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	

ARNICA MONTANA (UNII: O80TY208ZW)
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
TROLAMINE (UNII: 9O3K93S3TK)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-917-30	5 in 1 BOX	10/02/2017	
1		17 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 not final	part348	07/29/2017	

**Labeler** - Proficient Rx LP (079196022)

### Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(63187-917)

Revised: 11/2019

Proficient Rx LP