LIDOZEN- lidocaine hydrochloride, menthol patch
Village Pharma LLC

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.

Lidozen Patch

DRUG FACTS:

ACTIVE INGREDIENTS:

Lidocaine HCL 4.00%

Menthol 1.00%

Toplcal 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.

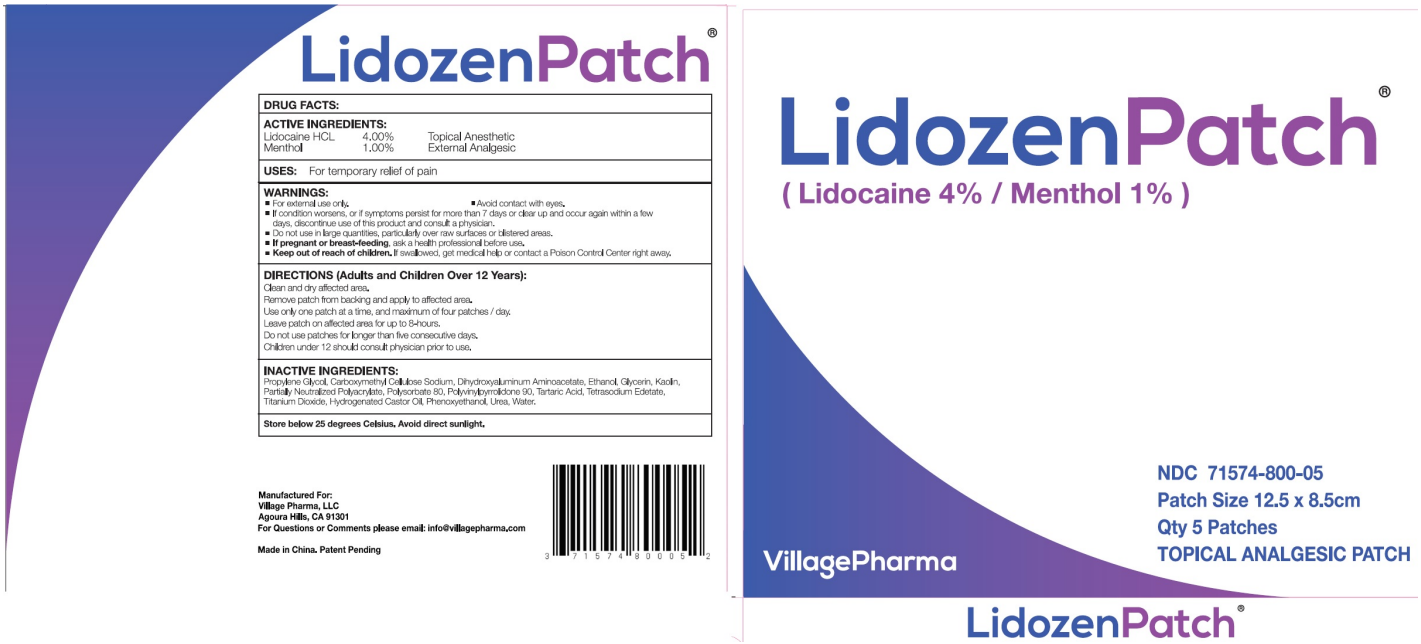
Children under 12 should consult physician prior to use.

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

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	

KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TARTARIC ACID (UNII: W4888I119H)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item 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 not final	part348	05/01/2019	

Labeler - Village Pharma LLC (080749749)

Revised: 9/2019 Village Pharma LLC