LIDOZEN GEL- lidocaine hydrochloride, menthol gel
Village Pharma LLC

Lidozen Gel

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):

Apply directly to affected area. Do not use more than four times per day.

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, Polysorate-80,

Sodium Lauryl Sulfate, Triethanolamine, FD&C Blue #1, FD&C Yellow #5.

Package Labeling:

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

LIDOZEN GEL

lidocaine hydrochloride, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71574-305
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 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (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: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:71574-305	120 mL in 1 BOTTLE, Type 0: Not a Combination		

1	NDC:71574-305-72	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/01/2022	

Labeler - Village Pharma LLC (080749749)

Revised: 11/2023

Village Pharma LLC