LENZAGEL- lidocaine hydrochloride, menthol gel
Aidarex Pharmaceuticals 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.

LenzaGel

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Active Ingredients:

Lidocaine HCL 4.00%

Menthol 1.00%

Purpose

Topical Analgesic

External Analgesic

Uses:

For temporary relief of pain associated with minor cuts, scrapes and minor skin irritations.

Warnings

- For external use only
- Avoid contact with eyes
- Do not apply to open wounds or damaged skin.
- If symptoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children.

If swallowed, consult physician.

- Do not bandage tightly
- If pregnant or breast feeding, contact physician prior to use.
- Do not use in large quantities, particularly over raw surfaces or blistered areas.

Directions

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

Other 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.

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Repackaged By :
Aidarex Pharmaceuticals LLC,
Corona, CA 92880

LENZAGEL

lidocaine hydrochloride, menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53217-026(NDC:45861-016)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 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)	

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
1	NDC:53217-026-01	120 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	03/01/2013	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 10/2013 Aidarex Pharmaceuticals LLC