LIDALL- lidocaine patch
MedVantage Pharmaceutical, 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.

LidAll Pain Relieving Patch

Warnings

For external use only

Do not use

■ other than directed

■ on wounds

■ on damaged skin

■if you are allergic to menthol

■ in large quantities, particularly over raw services or blistered areas

When using this product

■ avoid contact with the eyes or mucous membranes

■ do not bandage tightly

Stop use and ask a doctor

■ excessive irritation of the skin develops

■ condition worsens

■symptoms persist for more than 7 days

■ symptoms clear up and occur again within a few days

Active ingredients

Lidocaine 4%

Menthol 1%

Inactive ingredients

Aloe (Aloe Barbadensis) Leaf Juice, Diazolidinyl Urea, EDTA Disodium Salt, Glycerin, Iodopropynyl Butylcarbamate,

Methylparaben, Polysorbate 80, Propylparaben, Sodium Polyacrylate, Water

Keep out of reach of children.

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

Directions

Directions

■Clean and dry affected area. Cut open pouch and remove patch.

■Remove protective film and apply directly to affected area.

■Wash hands with soap after applying patch.

■Reseal pouch containing unused patches.

■Adults and children 12 years of age and older: Apply to affected area; change patch 1 to 2 times daily. Do not apply

to affected are more than 3 times daily.

■Children under 12 years of age: Consult a physician before use.

Purpose

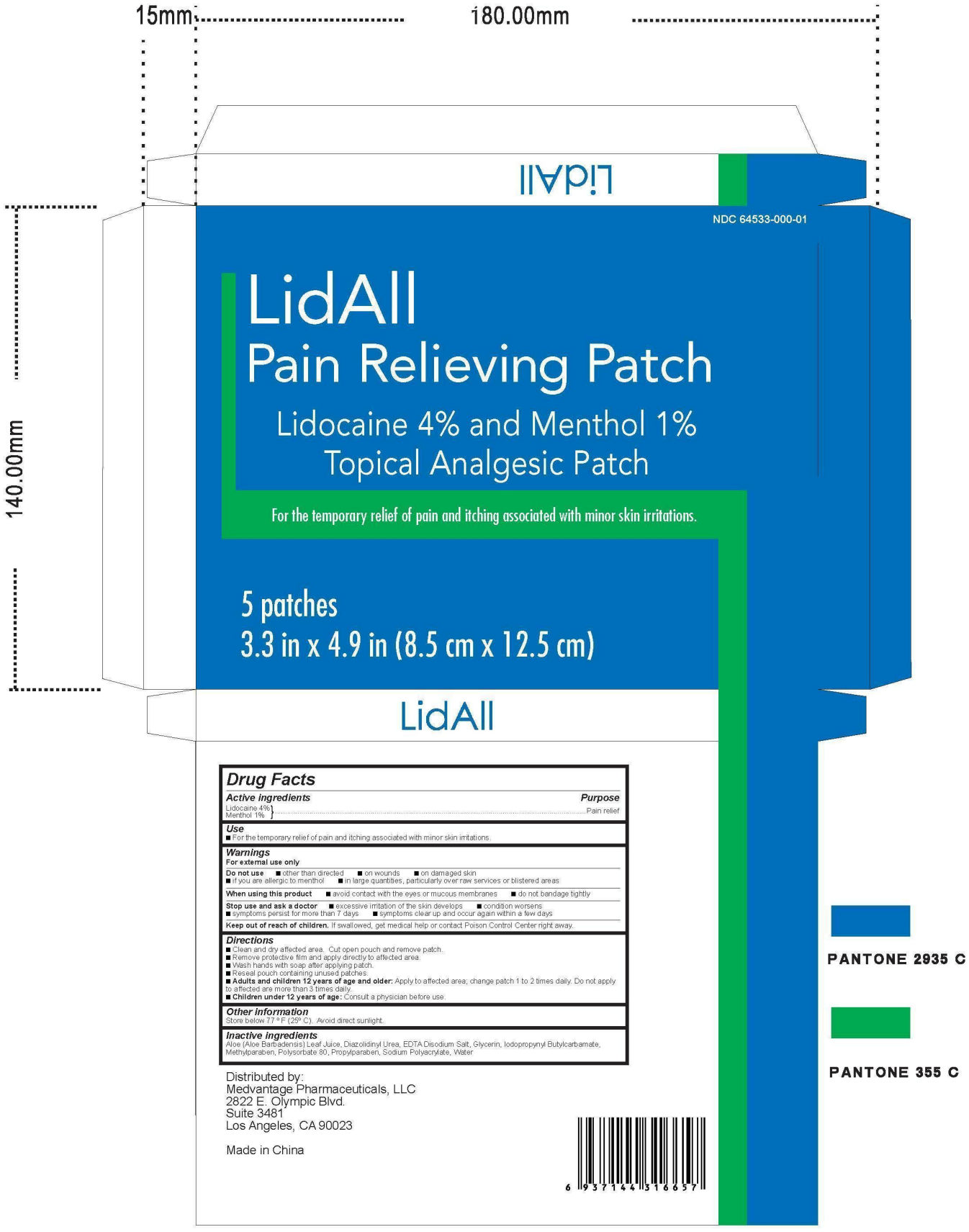
Pain relief

Use

■For the temporary relief of pain and itching associated with minor skin irritations.

Other information

Store below 77 º F (25º C). Avoid direct sunlight.



LIDALL

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64533-000
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE (UNII: V5VD430YW9)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETIC ACID (UNII: 9G34HU7RV0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64533-000-01	100 g in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2013	

Labeler - MedVantage Pharmaceutical, LLC (079094932)

Registrant - MedVantage Pharmaceutical, LLC (079094932)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(64533-000)

Revised: 4/2014 MedVantage Pharmaceutical, LLC