LIDONEXE- lidocaine, menthol patch
Patchwerx Labs, Inc.

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.

Lidonexe Patch

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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

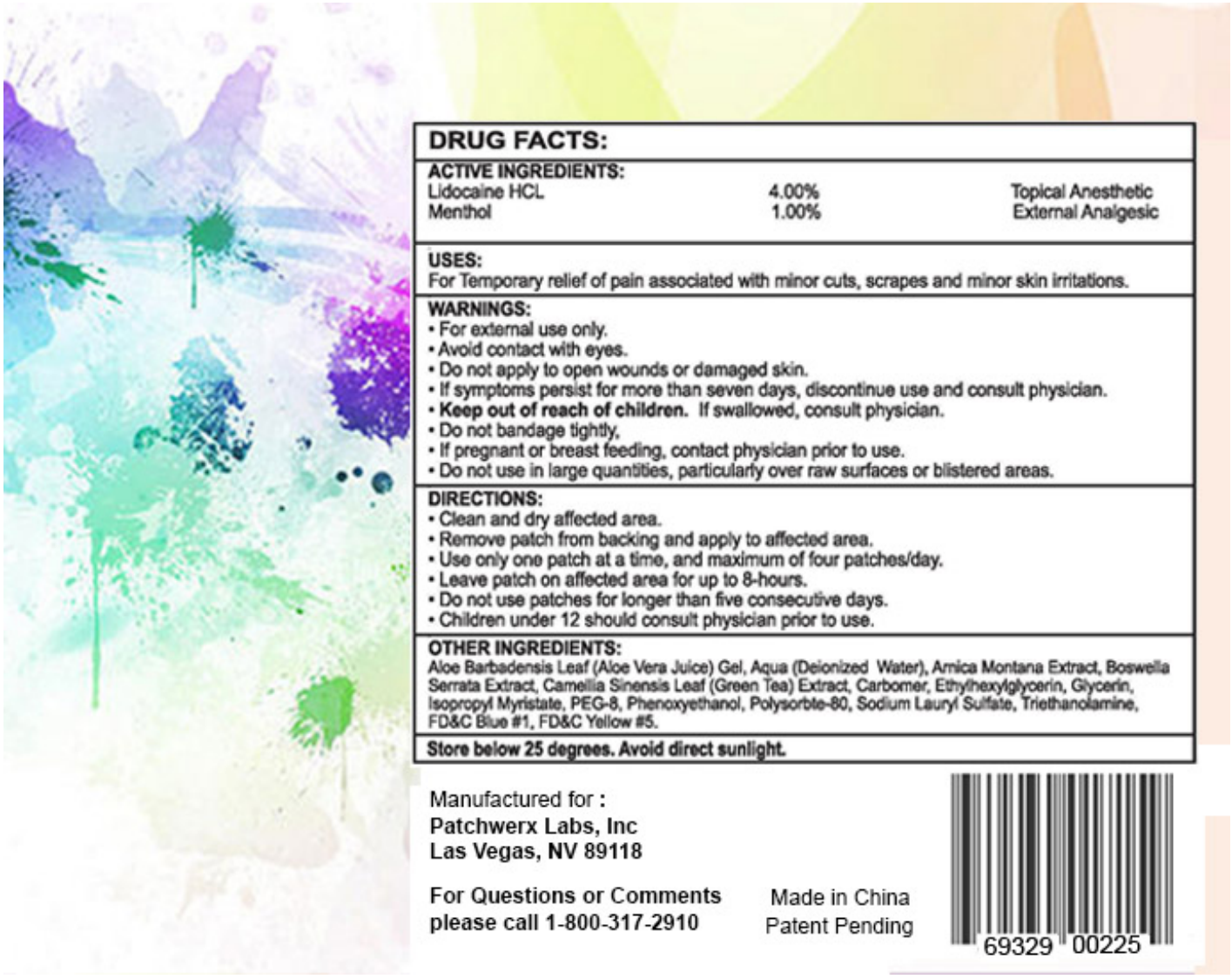
- Clean and dry affected area.
- Remove patch from backing and apply to affected area.
- Use only one patch at a time, and maximum of four patches/day.
- Leave patch on affected area for up to 8-hours.
- Do not use patches for longer than five consecutive days.
- Children under 12 should consult physician prior to use.

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.

Store below 25 degrees. Avoid direct sunlight.

Lidonexe 25 patches (69329 -002-25)



LIDONEXE

lidocaine, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69329-002
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**
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)	
ARNICA MONTANA (UNII: O80TY208ZW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69329-002-05	5 in 1 BOX		
1		10 g in 1 PATCH		
2	NDC:69329-002-25	25 in 1 BOX		
2		10 g in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/10/2014	

Labeler - Patchwerx Labs, Inc. (079584480)

Revised: 11/2014 Patchwerx Labs, Inc.