POINT RELIEF LIDOSPOT- lidocaine hcl, menthol patch
Fabrication Enterprises

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.

Point Relief LidoSpot ™ Patch

Drug Facts

Lidocaine HCl 4%

Menthol 1%

Topical Anesthetic

External Anesthetic

USES

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

WARNINGS

- For External use only. Use only as directed.
- Avoid contact with eyes and mucous membranes.
- If symptoms persist for more than 7 days, discontinue use and consult a physician
- If swallowed, consult a physician.

- Keep out of reach of children. Consult a physician prior to using on children under 12.

- Do not apply to open wounds or damaged skin.
- Do not use oils, lotions or powders on treatment area prior to application.
- Do not use with any bandage, wrap, stocking or similar device or garment.

- If pregnant or breast feeding, contact a physician prior to use.

DIRECTIONS

- Apply to treatment area.
- How to apply:
- Clean and dry treatment area.
- If customized size is needed, cut patch to the desired size/shape with scissors.
- Remove protective backing from patch to expose active ingredient and adhesive.
- Apply patch to treatment area.
- Use only one patch at a time. Use a maximum of four patches per day.
- Leave patch on treatment area for up to 12 hours.
- Do not use patches for longer than 5 consecutive days.

OTHER INGREDIENTS

Water, Glycerol, Sodium polyacrylate, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Arnica Montana Flower Extract, Boswellia Serrata Extract, Camellia Sinensis (Green Tea) Extract, Aluminiumglycinate,

Titaniumdioxide, Kaolin, Tween 80, Propylene glycol, Tartaric acid, PVP, Polyacrylic acid, Methylparaben, Propylparaben.

Store at room temperature

Avoid direct sunlight

Representative Labeling

POINT RELIEF LIDOSPOT

lidocaine hcl, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51452-727
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, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TARTARIC ACID (UNII: W4888I119H)	
PROPYLENE GLYCOL 1-(2-METHYLBUTYRATE) (UNII: 9Q5W5G6461)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
KAOLIN (UNII: 24H4NWX5CO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-727-01	5 in 1 POUCH	03/02/2016	
1		8 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	03/02/2016	

Labeler - Fabrication Enterprises (070577218)

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