LIDOCAINE PATCH- lidocaine 4% menthol 1% patch SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS

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.

Lidocaine 4% Plus Manthol 1% Patch 24 Hours

Active Ingredients

Lidocaine 4%	6	. Topical Anesthetic
Menthol 1%		. Topical Anesthetic

Purpose

For temporary relief of minor pain.

Dosage and Administration

Directions: Adults and children 12 years of age and over: Clean and dry affected area. Apply immediately upon removal from pouch. Peel off the first liner and apply exposed patch to affected area. Peel off second liner while applying the rest of patch. Remove patch after 24 hours. Discard patch after single use. Do not expose area to heat.

Children under 12 years of age: Consult a physician.

Warnings

For external use only.

Do not use

- if you are allergic to any active or inactive ingredients of this product
- on wounds or damaged, irretated, or sensitive skin
- with any other topical anesthetic
- for more than one week without consulting a doctor
- with a heating pad
- if pouch is damaged or open

When using this product

■ do not allow contact with the eyes

- use only as directed, read and follow all directions and warnings on this package
- do not bandage tightly or apply local heat
- Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.
- do not reuse patch

Stop use and ask a doctor if

- symptoms persist for more than seven days or clear up and occur again within a few days
- condition worsens
- localized skin reactions occur such as rash, pain, itching, redness, irritation, swelling or blistering.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children and pets.

If chewed or swallowed, get medical help or contact a Poison Control Center right away. (800-222-1222)

Other Safety Information

Store in a clean, dry place outside of direct sunlight. Store in original unopened pouch protected from moisture.

Inactive Ingredients

alicyclic hydrocarbon resin, mineral oil, polyester film, silicon-coated polyester film and styrene isoprene styrene block copolymer.

Questions

Questions? 1-866-760-6565, Monday - Friday 8:30 a.m - 4:30 p.m. EST

Manufactured for: AUM Pharmaceuticals Hauppauge, NY 11788

Made in USA From Domestic and Imported Components



LIDOCAINE PATCH

lidocaine 4% menthol 1% patch

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73317-6863

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) LIDOCAINE (UNII: 98PI200987)

Inactive Ingredients	
Ingredient Name	Strength
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (STYRENE/ISOPRENE 15/85) (UNII: 1SSZ 6HXE7P)	
HYDROGENATED C6-20 POLYOLEFIN (100 CST) (UNII: 39EYQ1W9RB)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color

Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:73317- 6863-5	15 in 1 CARTON	07/02/2021	
1	9 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information		
Marketing Start Marketing End Date Date	Application Number or Monograph Citation	Marketing Category
7/02/2021	part348	OTC monograph not final
7/02/2021	part348	

Labeler - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

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