

LIDOCAINE PATCH- lidocaine 4% 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 Patch 24 Hours

Active Ingredients

Lidocaine 4% Topical Anesthetic

Purpose

Temporarily relieves minor pain.

Dosage and Administration

Directions Adults and children over 12 years:

- clean and dry affected area
- carefully remove backing from patch starting at corner
- apply sticky side of patch to affected area
- use one patch for up to 24 hours. Discard patch after single use. **Children under 12 years of age:** consult a physician.

Warnings

For external use only.

Indications and Usage

Uses: Temporarily relieves minor pains.

When using this product

- use only as directed
- read and follow all directions and warnings on this carton
- do not allow contact with the eyes
- do not use at the same time as other topical analgesics
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not microwave

■ dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and consult a doctor

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling or blistering where the product was applied.

If pregnant or breastfeeding, ask a health professional before use.

Do not Use

- more than one patch on your body at a time
- on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor
- if you are allergic to any active or inactive ingredients
- if pouch is damaged or opened.

Keep out of reach of children and pets.

If 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. Protect from excessive moisture.

Inactive Ingredients

Styrene Isoprene Styrene block Copolymer, Alicyclic Saturated Hydrocarbon Resin, White Mineral Oil

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

DO NOT USE IF SEAL IS DAMAGED OR OPENED

Drug Facts (continued)

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 or pets.

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


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.

Other information store in a clean, dry place away from direct sunlight. Store in original unopened pouch protected from moisture.

Inactive ingredients: allylic hydrocarbon resin, mineral oil, polyester film, silicone-coated polyester film and styrene isoprene styrene block copolymer.

Questions? 1-866-760-6665, Monday - Friday 8:30 a.m. - 4:30 p.m. EST

Child-Resistant Packaging
Contains 1 Patch
2.91" x 2.17" (7.4 cm x 5.5 cm)

Manufactured for:

AUM Pharmaceuticals
Hauppauge, NY 11788

To open, cut here

NDC 73317-6866-5

Maximum Strength
Lidocaine 4% **24** Hours



Topical Pain Relief Patch

Desensitizes Aggravated Nerves

- Fast Acting
- Odor-Free, Super Flexible & Thin
- No-Mess, Single-Use Application
- Maximum Delivery Force Technology

MADE IN USA

Drug Facts	
Active ingredient Lidocaine 4%	Purpose Topical anesthetic
Use For temporary relief of minor pain	
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, irritated, or sensitive skin ■ with any other topical anesthetic ■ for more than one week without consulting a doctor ■ with a heating pad.	
When using this product ■ do not allow contact with 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 effect if a child or pet ingests this patch ■ do not reuse patch.	



NDC 73317-6866-5


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Topical Pain Relief Patch

Desensitizes Aggravated Nerves

- Fast Acting
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- No-Mess, Single-Use Application
- Maximum Drug Delivery Force Technology

15 Patches
2.91 IN. X 2.17 IN. (7.4 cm X 5.5 cm)
(15 Envelopes Containing 1 Patch Each)



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Other information store in a clean, dry place away from direct sunlight. Store in original unopened pouch protected from moisture.


Inactive ingredients: alicyclic hydrocarbon resin, mineral oil, polyester film, silicone-coated polyester film and styrene isoprene styrene block copolymer.

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Child-Resistant Packaging



N 3 73317 68665 7



Manufactured for:
AUM Pharmaceuticals
Hauppauge, NY 11788
Made in USA

LIDOCAINE PATCH

lidocaine 4% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73317-6866
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

Inactive Ingredients

Ingredient Name	Strength
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (STYRENE/ISOPRENE 15/85) (UNII: 1SSZ6HXE7P)	
HYDROGENATED C6-20 POLYOLEFIN (100 CST) (UNII: 39EYQ1W9RB)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73317-6866-5	15 in 1 CARTON	04/21/2021	
1		9 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/21/2021	

Labeler - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)