

LIDOCAINE 4% PATCH- lidocaine 4% patch
SOLA 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% Topical Patch

Active Ingredients

Lidocaine 4%

Purpose

Topical Anesthetic

Uses

For the temporary relief of pain

Warnings

For external use only

Do not use:

- More than 1 patch at a time
- On wounds or damaged skin
- With a heating pad
- If you are allergic to any ingredients of this product

When using this product:

- Use only as directed
- Avoid contact with the eyes, mucous membranes, or rashes
- Do not bandage tightly

Stop use and ask a doctor if:

- Localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- Conditions worsen
- Symptoms persist for more than 7 days
- Symptoms clear up and occur again within a few days

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DirectionsAdults and children 12 years of age or over:

- Clean and dry the affected area
- Open pouch and remove one patch
- Apply 1 patch at a time to affected area; not more than 3 to 4 times daily
- Reseal pouch containing unused patches after each use
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age:

- Consult a doctor

Other Information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Other Ingredients

Acrylic Adhesive, Flaxseed oil, and Polysorbate 80

Questions or comments? 866-747-7365

Lidocaine 4% Patch

NDC 70512-014-30

Qty: 30 Flex Patches

(5 per resealable pouch) x 6

Manufactured for:

SOLA Pharmaceuticals

Baton Rouge, LA 70810



LIDOCAINE 4% PATCH

lidocaine 4% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70512-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
FLAX SEED (UNII: 4110YT348C)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ACRYLIC ACID (UNII: J94PBK7X8S)	

Product Characteristics

Color		Score	
Shape	RECTANGLE (White Flexible Patch)	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70512-014-30	6 in 1 BOX	05/24/2021	
1		5 g in 1 POUCH; 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	05/24/2021	

Labeler - SOLA Pharmaceuticals (080121345)

Revised: 6/2021

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