

LIDAFLEX- lidocaine 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.

LidaFlex

Active ingredients:

Lidocaine HCL 4%

Purpose:

Topical Anesthetic

Uses:

For 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.

Directions

Adults and Children 12 years of age and 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

Acrylic Adhesive, Flaxseed oil, and Polysorbate 80

Manufactured for:

SOLA Pharmaceuticals

655 Highlandia Dr. Ste B

Baton Rouge, LA 70810

For questions for comments call 866-747-7365

LidaFlex Patch

Topical Pain Patch

For temporary pain relief

NDC 70512-012-30

Qty: 30 Flex Patches

(5 per Resealable Pouch) x 6



LIDAFLEX

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70512-012
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
ACRYLIC ACID (UNII: J94PBK7X8S)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FLAX SEED (UNII: 4110YT348C)	

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:70512-012-30	3 in 1 BOX	01/27/2021	
1		1 g in 1 POUCH; 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	01/27/2021	

Labeler - SOLA Pharmaceuticals (080121345)