

SYNOFLEX PATCH- synoflex patch 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.

SynoFlex Patch

Active Ingredients

Lidocaine Hcl 4%

Menthol 5%

Purpose

Topical Anesthetic

Uses

For the temporary relief of pain

Warnings

For external use only

Do not use

- More than 1 patch on your body at a time or on cut, irritated, or swollen skin
- On puncture wounds
- For more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all directions and warnings on this label
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken, or irritated skin
- do not allow contact with the eyes and mucous membranes
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not use at the same time as other topical analgesics
- dispose of used patch in a 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 ask a doctor if

- 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 breast-feeding

ask a healthcare professional before use.

Keep out of reach of children and pets

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children over 12 years: Clean and dry the affected area

- Open pouch and remove one patch
- Remove the protective film from the patch and apply patch to the affected area
- Reseal pouch containing unused patches after each use
- Use 1 patch for up to 12 hours

Children 12 years or younger: ask a doctor

Other Information

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

Other Ingredients

Acrylic Adhesive

Questions or comments?

866-747-7365

Manufactured for:

Sola Pharmaceuticals LLC

Baton Rouge, LA 70810

SynoFlex Patch

Topical Pain Patch

For temporary relief of pain

NDC 70512-015-15

Qty: 15 Flex Patches

(5 per Resealable Pouch) x 3



SYNOFLEX PATCH

synoflex patch patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70512-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

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:70512-015-15	3 in 1 BOX	04/28/2022	
1		5 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	04/28/2022	

Labeler - Sola Pharmaceuticals (080121345)

Revised: 5/2022

Sola Pharmaceuticals