

ASPERFLEX- lidocaine patch
Akron Pharma Inc.

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.

AspeFlex
Tough on Pain
Lidocaine Patch 4%

Drug Facts

Active Ingredient

Lidocaine 4%

Purpose

Topical anesthetic

Uses

for the temporary relief of pain

Warnings

For external use only

Do not use

- on puncture wounds, cuts, irritated or swollen skin
- more than 1 patch on your body at a time or with other topical analgesics at the same time
- with a heating pad or apply local heat to the area of use

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 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 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 or symptoms persist for more than 7 days

- symptoms clear up and occur again within a few days
- redness or irritation develops
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

adults and children over 12 years:

- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- use 1 patch at a time and not more than 3 to 4 times daily

children 12 years or younger: consult a doctor

Other Information

store at room temperature 15°-30°C (59°-86°F).

Inactive ingredients

aluminum glycinate, glycerin, methyl acrylate, polyacrylic acid, polysorbate 80, propylene glycol, sodium polyacrylate, tartaric acid, titanium dioxide urea, poval, alcohol, water

Questions or Comments?

Call toll-free 1-877-255-6999.

Manufactured for:

Akron Pharma Inc.,

Fairfield, NJ-07004

www.akronpharma.com



ASPERFLEX

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-4456
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
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL ACRYLATE (UNII: WC487PR91H)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)

TARTARIC ACID (UNII: W4888I119H)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

UREA (UNII: 8W8T17847W)

ALCOHOL (UNII: 3K9958V90M)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-4456-5	5 in 1 CARTON	11/04/2021	
1		0.246 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	11/04/2021	

Labeler - Akron Pharma Inc. (067878881)

Revised: 2/2023

Akron Pharma Inc.