

FIRSTCARE PAIN RELIEF GEL PATCH- lidocaine patch
USpharma Ltd

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.

FirstCare Pain Relief Gel Patch Lidocaine 4%

Active ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Uses

Temporarily relieves minor 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 carton.
- do not allow contacts 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 worsen
- 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 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.

Directions

adults and children over 12 years:

- clean and dry affected area
- remove film from patch
- carefully apply patch to affected area
- use 1 patch for up to 12 hours

children 12 years or younger: ask a doctor

Inactive ingredients

polyvinyl alcohol, non-crystalizing sorbitol solution, polyacrylic acid, glycerin, carboxymethylcellulose sodium, colloidal silicon dioxide, titanium dioxide, propylene glycol, tartaric acid, magnesium hydroxide, sodium polyacrylate, purified water

Package/Label Principal Display Panel

FIRST CARE™

*****MADE IN USA*****

LASTS UP TO 12 HOURS

MAXIMUM STRENGTH**

PAIN RELIEF GEL PATCH

FOR BACK, SHOULDER, NECK & JOINTS

Lidocaine 4%

Targets Muscle and Nerve Pain

Odor & Paraben Free

3-15/16" x 5-1/2" (10 cm x 14 cm)

NDC 71594-602-05

5 PATCHES

Individually sealed in child resistant packages



FIRSTCARE PAIN RELIEF GEL PATCH

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71594-602
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	246 mg

Inactive Ingredients

Ingredient Name	Strength
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SORBITOL (UNII: 506T60A25R)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TARTARIC ACID (UNII: W48881119H)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71594-602-05	5 in 1 CARTON	10/25/2019	
1		1 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	10/25/2019	

Labeler - USpharma Ltd (080664601)

Registrant - USpharma Ltd (080664601)

Establishment

Name	Address	ID/FEI	Business Operations
USpharma Ltd		080664601	manufacture(71594-602) , pack(71594-602)

Revised: 10/2019

USpharma Ltd