

ASPERCREME WITH LIDOCAINE- lidocaine patch
Chattem, 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.

Aspercreme Lidocaine Patch

Aspercreme® LIDOCAINE PATCH

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
- do not bandage tightly
- avoid contact with the eyes
- 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.

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

Inactive ingredients

aluminum glycinate, aluminum hydroxide, cellulose gum, glycerin, methyl acrylate/2-ethylhexyl acrylate copolymer, methylparaben, nonoxynol-30, polyacrylic acid, polysorbate 80, propylene glycol, silica, sodium polyacrylate, tartaric acid, titanium dioxide, urea, water

PRINCIPAL DISPLAY PANEL

Aspercreme
Lidocaine Patch



ASPERCREME WITH LIDOCAINE

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0584
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)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYGALIC ACID (UNII: XCC6WEA55L)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	
NONOXYNOL-30 (UNII: JJX07DG188)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0584-0	5 in 1 CARTON	02/01/2016	
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	02/01/2016	

Labeler - Chattem, Inc. (003336013)

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Chattem, Inc.