

CORALITE LIDOCAINE PAIN RELIEF- lidocaine patch

United Exchange Corp.

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.

Active ingredient

Purpose

Lidocaine 4%.....Topical analgesic

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 pouch.
- 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 products that can

product that can produce serious adverse effects if a child or pet chews or ingests this patch.

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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

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 for up to 12 hours

Inactive ingredients □ aluminum glycinate, aluminum hydroxide, cellulose gum, glycerin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, silicon dioxide, sodium polyacrylate, tartaric acid, titanium dioxide, urea, water □ **Distributed by**

Distributed by:

United Exchange Corp.

17211 Valley View Ave.

Cerritos, CA 90703 U.S.A.

✂ Cut open pouch

Coralite[®]

Compare to **ASPERCREME**[®]
Lidocaine Patch active ingredient*

4% LIDOCAINE

PAIN PATCH

ODOR FREE • MAXIMUM STRENGTH

- FAST ACTING
- NUMBS PAIN RECEPTORS
- GREAT FOR ARTHRITIS PAIN RELIEF

MUSCLE
JOINT



1 PATCH

3.94 in. x 5.51 in.
(10 cm X 14 cm) each



10.16 VO.1



LOT & EXP.

United Exchange Corp.
17211 Valley View Ave.
Cerritos, CA 90703 U.S.A.
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Toll Free: 1 800 814 8028
Made in China



Distributed by:



*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Aspercreme® Lidocaine Patch.

Drug Facts	<p>Active Ingredient Lidocaine 4%Topical analgesic</p> <p>Purpose</p> <p>Uses temporarily relieves minor pain</p> <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>When using this product</p> <ul style="list-style-type: none"> use only as directed. Read and follow all directions and warnings on this pouch. 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. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions adults and children over 12 years:</p> <ul style="list-style-type: none"> 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 for up to 12 hours <p>Inactive ingredients aluminum glycinate, aluminum hydroxide, cellulose gum, glycerin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, silicon dioxide, sodium polyacrylate, tartaric acid, titanium dioxide, urea, water</p> <p>Questions? call 1-800-814-8028</p>
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ODOR FREE • MAXIMUM STRENGTH
PAIN PATCH
 4% LIDOCAINE



Cut open pouch

CORALITE LIDOCAINE PAIN RELIEF

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	560 mg

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-159-01	1 in 1 POUCH; Type 0: Not a Combination Product	01/23/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/23/2017	

Labeler - United Exchange Corp. (840130579)

Revised: 1/2017

United Exchange Corp.