

**CAPSAICIN HOT PATCHES- capsaicin patch**  
**Cardinal Health, 110 dba LEADER**

*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.*

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**Leader Capsaicin Hot Patches**

**For External Use Only**

- Discontinue use at least one hour prior to bath / shower / swimming; do not use immediately after bath / shower / swimming.
- Allergy alert: if you are allergic or suspect you are allergic to the ingredients listed below, including chili peppers.. consults with your physician before use.

**Uses**

Temporary relief of minor pain associated with:

- Arthritis
- Minor backache
- Strains
- Sprains
- Bruises

**Purpose**

Temporary relief of minor pain associated with: arthritis, minor backache, muscle strains, muschle sprains, bruises

**Active Ingredients**

Capsaicin: 0.025%.....Topical Analgesic

**Inactive Ingredients:**

Hydrogenated Poly, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Petroleum, Styrene / Isoprene Copolymer

**Directions for Use:**

**For Use on Adults and Childrens 12 Years of Age or Older**

- Clean and dru affected area; ensure area is fully dry before application
- Remove patch from film
- Apply to treatment site

- Patch may be trimmed to best fit treatment site; trim patch before removing film
- Wash hands after application
- Discard after single use

**Caution:**

- Take care when using on elderly or incapacitated persons
- Do not use more than 8 hours
- Do not use the Capsaicin Heat Patch more than 3-4 times daily
- Do not exceed 7 days of continuous use

**Keep Out of Reach of Children**

if swallowed, contact a poison control center immediately.

**Storage and Care:**

- One time use only; do not attempt to reuse the product
- avoid storage in direct sunlight
- Protect patch from excessive moisture

**Do Not Use:**

- On areas with sensitive skin, open wounds or previous burns
- with pain rubs, medicated lotions, creams or ointments
- with other forms of heat therapy, including heating pads, or multiples of this treatment on a single treatment site

**Use Only as Directed:**

- Follow the below directions for use.
- Avoid contact with eyes, mucous membranes or skin rashes.

**Stop Use immediately and Seek Medical Attention if:**

- Rash, itching or excessive skin irritation develops
- Conditions worsens
- Symptoms persist more than 7 days
- Symptoms clear, and reoccur within a few days

**QUESTIONS**

TOLL-FREE

Customer Care Help Line  
866-326-1313

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017

Made in China

**LABEL**

**LEADER**

RESEAL AFTER OPENING

Targeted Warming

## Capsaicin Heat Patch

Capsaicin, 0.025% | Topical Analgesic

<b>Drug Facts</b>	
<b>Active ingredient</b> .....	<b>Purpose</b> Capsaicin 0.025%..... Topical analgesic
<b>Use</b> Temporary relief of minor pain associated with: arthritis, minor backache, muscle strains, muscle sprains, bruises	
<b>Warnings</b> For external use only <b>Allergy alert:</b> Do not use if you are allergic to natural rubber or latex, capsaicin or any ingredient in this product. # Discontinue use at least one hour prior to bath/shower/swimming; do not use immediately after bath/shower/swimming # <b>Allergy alert:</b> If you are allergic or suspect you are allergic to the ingredients listed below, including chili peppers, consult with your physician before use. Do not use # On areas with sensitive skin, open wounds or previous burns # With pain rubs, medicated lotions, creams or ointments # With other forms of heat therapy, including heating pads or multiples of this treatment on a single treatment site. Use only as directed # Follow the below direction for use # Avoid contact with eyes, mucus membranes or skin rashes. Stop use immediately and seek medical attention if # Rash, itching or excessive skin irritation develops # Condition worsens # Symptoms persist more than 7 days # Symptoms clear and recur within a few days. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, contact a poison control center 800-322-1222 immediately.	
<b>Directions</b> Adults and children 12 years of age and over: Clean and dry affected area; ensure area is fully dry before application. Remove patch from film. Apply to treatment site. Patch may be trimmed to best fit treatment site; trim patch before removing film. Wash hands after application. Discard after single use. Reseal pouch after opening.	
<b>Caution</b> # Take care when using on elderly or incapacitated persons # Do not use for more than 8 hours # Do not use the Capsaicin Heat Patch more than 3-4 times daily # Do not exceed 7 days of continued use.	
<b>Other information</b> # One time use only; do not attempt to reuse the product # Avoid storage in direct sunlight # Protect patch from excessive moisture.	
<b>Inactive ingredients</b> hydrogenated poly, pentan-1-thiyl tetra- <i>cis</i> -4-butyl hydroxyhydroximate, petroleum, styrene/isoprene copolymer	
<b>Questions or comments?</b> Call 1-866-328-1313	

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www.leader.com 1-800-380-6303  
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92-73046 06/20 VC510046

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.

LOT EXP

## CAPSAICIN HOT PATCHES

capsaicin patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0556
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAPSAICIN</b> (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength

<b>HYDROGENATED POLYDECENE (550 MW)</b> (UNII: U333RI6EB7)	
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)	
<b>LIQUID PETROLEUM</b> (UNII: 6ZAE7X688J)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	RECTANGLE	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0556-1	2 in 1 BOX	06/01/2020	
1		9 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	06/01/2017	

### Labeler - Cardinal Health, 110 dba LEADER (063997360)

### Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(70000-0556)

Revised: 1/2023

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