

2-COUNT HEAT PATCHES- capsaicin patch
QUALITY CHOICE (Chain Drug Marketing Association)

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.

HEAT PATCH

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.

Active Ingredients

Capsaicin: 0.025%.....Topical Analgesic

Inactive Ingredients:

Hydrogenated Poly, Pentaerythryl 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 treatement site
- Patch may be trimmerd to best fit treatment site; trim patch before removing film
- Wash hands after application
- Discard after signle use

Caution:

- Take care when using on elderly ot incapacited 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 continue 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, mucus 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

Customer Care Help Line

248-449-9300

www.qualitychoice.com

LABEL

Distributed by C.D.M.A., Inc.

43157 W. Nine Mile

Novi, MI 48375

Made in China



NDC 63868-0308-02



ITEM NO. 89-904-2P40

Topical Analgesic

Capsaicin Heat Patch

Single Use Solution

Targeted No Mess Relief
Comfortable Fabric
Stays in Place
Long Lasting
Pain Relief



2 patches - 5.25 in. x 7 in. (13.335 cm x 17.78 cm)

Capsaicin Heat Patch

Single Use Solution

What is capsaicin?
Capsaicin is a naturally occurring ingredient in chili peppers.

How does capsaicin work?
Extract from the chili pepper plant has proven effective in decreasing intensity and blocking pain signals within the body. Blocking these pain signals can help to provide relief for common aches and pains, including minor backaches, arthritis, pains, strains and bruises.

DRUG FACTS
Active Ingredient **Purpose**
Capsaicin: 0.025% Topical Analgesic

Uses Temporary relief of minor pain associated with: ■ Arthritis ■ Minor backache ■ Strains ■ Sprains ■ Bruises

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Directions for Use

For Use on Adults and Children 12 Years of Age or Older: ■ 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.

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Inactive Ingredients

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



GS1 DATAMATRIX
BAR CODE LABEL
PLACEMENT

(DO NOT PRINT)

LOT

EXP



Distributed by C.D.M.A., Inc.®
43157 1st Nine Mile
Novi, MI 48375
www.qualitychoice.com
Questions: 248-449-9300

Made in China
#92-89046 08/17



2-COUNT HEAT PATCHES

capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-308
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-308-02	2 in 1 BOX	06/01/2017	
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 - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)**Establishment**

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(63868-308)

Revised: 6/2017

QUALITY CHOICE (Chain Drug Marketing Association)