2-COUNT HEAT PATCHES- capsaicin patch Chain Drug Consortium, LLC

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 immediatelty after bath / shower / swimming.
- Allergy alert: if you are allergic or suspect you are allergic to the ingredients listed below, including chili perppers.. consults with your physician before use.

Uses

Temporary relief of minor pain associated with:

- Arthiritis
- Minor backache
- Strains
- Sprains
- Bruises

Purpose

Temporary relief of minor pain.

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 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 oinments
- with other forms of heat theraphy, including heating pads, or multiples of this treatment on a single treatement site

Use Only as Directed:

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

Stop Use immediately and Seek Medical Attention if:

- Rash, itching or excessive skin irritation develops
- Conditions worsens
- Symptons 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

DIST. BY Pharmacy Value Alliance, LLC 407 East Lancaster Avenue Wayne, PA 19087

Made in China



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

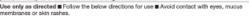
Active Ingredient..... Purpose



Warnings For External Use Only

■ Discontinue use at least one hour prior to bath/shower/swimming; do not use immediately after bath/shower/swimming. ■ Allengy after if you are allergic or suspect you are allergic to the ingredients lated below, including chill peppers. Consult with your physician better 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.



Stop use immediately and seek medical attention if:

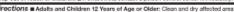
Rash, fiching or excessive skin irritation develops

Condition worsers

Symptoms persist more than 7 days

Symptoms clear and recover within a few days.

ep out of reach of children: If swallowed, contact a poison control center immediately



Directions adults and Children 12 Years of Age or Older Clean and Ay affected area; ensure area is fully dry before application. Remove patch from film. Apply to treatment site. Patch may be frimmed to beat fit treatment site; trim patch before removing film. Wash hands after application. Discard after single use.



■ 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

Storage and Care
One time use only; do not attempt to reuse the product
Avoid storage is direct sunlight
Protect patch from excessive moisture.

Inactive Ingredients
Hydrogenated Poly, Pentaerythrityl Tetra-di-t-butyl Hydroxythydrocinnamate, Petroleum,
Shyener/Soprene Copolymer





TOLL-FREE CUSTOMER CARE HELP LINE 866-326-1313



GS1 DATAMATRIX BAR CODE LABEL PLACEMENT

2-COUNT HEAT PATCHES

capsaicin patch

Product Information

HUMAN OTC DRUG NDC:68016-067 Product Type Item Code (Source)

TOPICAL **Route of Administration**

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

8	
Ingredient Name	Strength
HYDRO GENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDRO XYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
LIQUID PETROLEUM (UNII: 6ZAE7X688J)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	

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Product Characteristics			
Color		Score	
Shape	RECTANGLE	Size	

Flavor	Imprint Code	
Contains		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-067-02	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 - Chain Drug Consortium, LLC (101668460)

Establishment				
Name	Address	ID/FEI	Business Operations	
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(68016-067)	

Revised: 6/2017 Chain Drug Consortium, LLC