

CAPSAICIN HEAT PATCHES PAIN RELIEF- capsaicin patch

Rite Aid

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.

CAPSAICIN HEAT PATCH PAIN RELIEF PATCH

Active Ingredients

Capsaicin: 0.025%.....Topical Analgesic

Purpose

Topical Analgesic

Uses

Temporary relief of minor pain of muscles and joints associated with:

- Arthritis
- Minor backache
- Strains
- Sprains
- Bruises

Warnings

For External Use Only

Allergy alert

If you are allergic or suspect you are allergic to the ingredients of this product, including chill peppers, consult with your physician before use.

Do Not Use:

- On wounds or damaged skin
- with pain rubs, medicated lotions, creams, or ointments
- with heating pads

When Using this product

- Use only as directed
- Avoid contact with eyes, mucous membranes or rashes
- do not bandage tightly
- discontinue use at least 1 hour before a bath or shower
- do not use immediately after a bath or shower
- do not microwave

- dispose of used patch in a manner that always keeps products 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 ingest this patch.

Stop Use and ask a doctor if:

- Skin reactions such as redness, itching, rash, excessive irritation, burning sensation, swelling or blistering occur
- Conditions worsens
- Symptoms persist more than 7 days
- Symptoms clear, and reoccur 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 (1-800-222-1222) immediately.

Inactive Ingredients:

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

Directions:

Adults and Children 12 Years of Age and over:

- Clean and dry affected area
- Remove patch from film
- Apply to affected area not more than 3 to 4 times daily
- use one patch for up to 8 hours
- Discard after single use
- Children under 12 years of age: consult a physician

Other Information

- Avoid storage in direct sunlight
- Protect patch from excessive moisture

Inactive Ingredients

hydrogenated C6-20 polyolefin, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, petroleum, styrene/isoprene copolymer

QUESTIONS

866-326-1313 Monday - Friday 8:30 am -4:30 pm CST

LABEL



CAPSAICIN HEAT PATCHES PAIN RELIEF

capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-4210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
LIQUID PETROLEUM (UNII: 6ZAE7X688J)	

STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (UNII: K7S96QM8DV)	
HYDROGENATED C6-20 POLYOLEFIN (100 CST) (UNII: 39EYQ1W9RB)	

Product Characteristics

Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4210-3	3 in 1 BOX	08/01/2022	
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	08/01/2022	

Labeler - Rite Aid (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(11822-4210)

Revised: 8/2022

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