

CAPSAICIN- capsaicin patch
PHARMACURE, INC.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active Ingredient

Capsaicin 0.025%

Purpose

Topical Anesthetic

Uses

Temporarily relieves mild to moderate aches and pains of muscles and joints associated with muscle soreness, strains, sprains, arthritis, simple backache, muscle stiffness, bruises.

Warnings

For external use only. Use only as directed or as directed by a health care professional.

Do not use:

- On wounds, cuts, damaged or infected skin.
- On eyes, mouth, genitals, or any other mucous membranes.

Allergy Alert: if you are allergic to capsicum or chili peppers or any inactive ingredient of this product, contact a doctor before use.

When using this product:

- You may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation generally disappears after several days.
- Avoid contact with the eyes, lips, nose and mucous membranes.
- Do not tightly wrap or bandage the treated area.
- Do not apply heat to the treated area immediately before or after use.

Stop use and ask a physician:

- rash, itching or excessive skin irritation develops.
- conditions worsen.
- symptoms persist for more than 7 days.

- symptoms clear up and occur again within a few days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children and pets

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

Adults and children 18 years of age and older:

Apply 1 patch to the affected area of intact skin up to 3 times a day. Do not leave patch on for more than 8 hours at a time.

INSTRUCTIONS FOR USE :

Clean and dry the affected area.

Open pouch and remove one patch.

Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.

Wash hands with soap and water after handling the patches.

Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.

Discontinue use at least one hour prior to bath, shower, or swimming; do not use immediately after bath, shower, or swimming.

Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

Children under 18 years: Ask a physician

Inactive ingredients

Adhesive, myrrh gum, zinc oxide.

Other information

Some individuals may not experience pain relief until several minutes or hours after applying the patch. Store in a cool, dry place. Protect the product from excessive moisture or sunlight. Store at 67-77°F (19-25°C).

Label

DRUG FACTS

ACTIVE INGREDIENTS:

Capsaicin 0.025%

Purpose

Topical Anesthetic

USES:

For temporary relief of minor aches & pains of muscles & joints associated with arthritis, simple backache, strains, bruises, and sprains.

DIRECTIONS:

Adults and children 18 years and over: Apply 1 patch to the affected area of intact skin up to 3 times a day. Do not leave patch on for more than 8 hours at a time.

INSTRUCTIONS FOR USE:

- Clean and dry the affected area.
- Open pouch and remove one patch.
- Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.
- Wash hands with soap and water after handling the patches.
- Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.
- Discontinue use at least 1 hour before a bath or shower and do not use immediately after a bath or shower.
- Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of out patches where children and pets cannot get to them. Children under 18 years: ask a physician.

WARNINGS:

- For external use only. Use only as directed or as directed by a health professional.
- Do not use: On wounds, cuts, damaged or infected skin. On eyes, mouth, genitals, or any other mucous membranes.
- Stop use and ask a physician:
 - If rash, itching or excessive skin irritation develops.
 - If conditions worsen.
 - If symptoms persist for more than 7 days.
 - If symptoms clear up and occur again within a few days.
- Keep out of reach of children and pets.
- If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.
- Allergy Alert: If you are allergic to any ingredients of this product or chili peppers contact a doctor before use.
- When using this product: you may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation generally disappears after several days.
- Do not apply heat to the treated area immediately before or after use.

OTHER INFORMATION:

- Some individuals may not experience pain relief until several minutes or hours after applying the patch.
- Store in a cool, dry place.
- Protect product from excessive moisture or sunlight.
- Store at 67-77° F (19-25° C).

INACTIVE INGREDIENTS:

Adhesive, Myrrh Gum, Zinc Oxide.

Manufactured for:

PHARMACURE

For questions or comments
email info@pharmacure.info

CAPSAICIN 0.025% PATCH

EXTERNAL ANESTHETIC

PROVIDES WARMING
PAIN RELIEF

10 PATCHES

CAPSAICIN

capsaicin patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:79643-002
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
MYRRH (UNII: JC71GJ1F3L)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79643-002-01	10 in 1 BOX	02/02/2021	
1		100 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
unapproved drug other		02/02/2021	

Labeler - PHARMACURE, INC. (055983858)

Revised: 3/2023

PHARMACURE, INC.