

CAPSAICIN- capsaicin patch

Alexso, Inc

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 Patch

CAPSAICIN – Capsaicin 0.025% Patch

Alexso, Inc.

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 0.025% Cream

Drug Facts

Active ingredient

Capsaicin 0.025%

Purpose

External analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints due to:

- arthritis
- simple backache
- strains
- bruises
- sprains

Warnings

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

Read all warnings and directions before use.

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

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:

- If pregnant or breast feeding
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.
- If severe burning persists or blistering occurs

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center 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.

- 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.
- 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

Other information

Store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

Aqua (Deionized Water), Sodium Polyacrylate, Glycerin, Sorbitol, Sodium Cellulose Glycolate, Polysorbate 80, Lemon Oil, Aluminum Glycinate, Eucalyptus Oil, Methylparaben, EDTA Disodium Salt

PRINCIPAL DISPLAY PANEL

Capsaicin 0.025% Patch

NDC 50488-2025-1

10 Patches (5 per Resealable Pouch)

Alexso, Inc



CAPSAICIN			
capsaicin patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-2025
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
WATER (UNII: 059QF0KO0R)			
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)			
GLYCERIN (UNII: PDC6A3C0OX)			
SORBITOL (UNII: 506T60A25R)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			

LEMON OIL (UNII: 19GRO824LL)				
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-2025-1	2 in 1 BOX	01/08/2020	
1		5 in 1 POUCH		
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
OTC monograph not final		part348	01/08/2020	

Labeler - Alexso, Inc (963338061)