

**CAPSAICIN- capsaicin patch  
SA3, 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.*

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**Capsaicin Patch**

**CAPSAICIN - Capsaicin 0.025% Patch  
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**Capsaicin 0.025% Patch**

***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

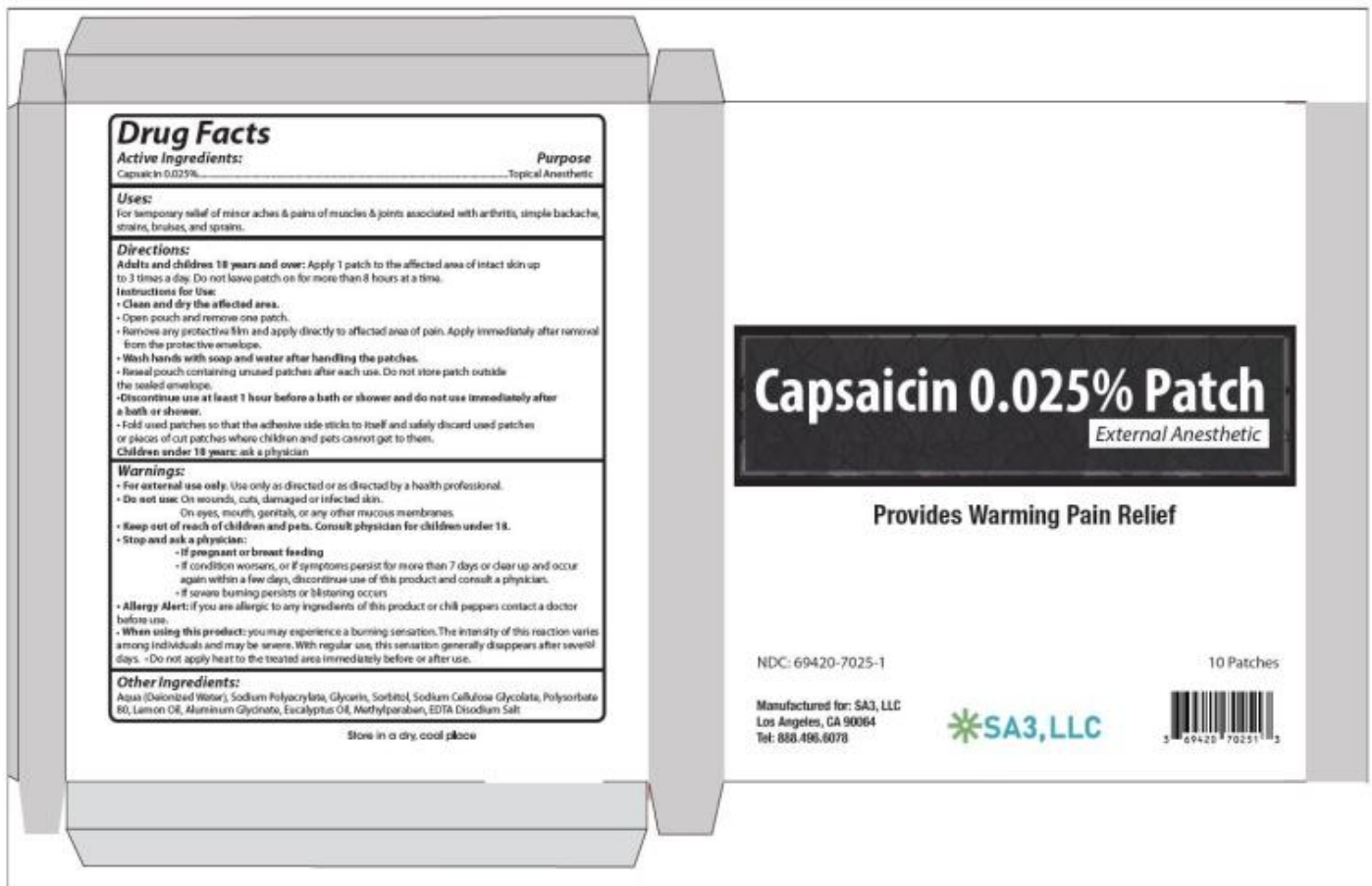
## PRINCIPAL DISPLAY PANEL

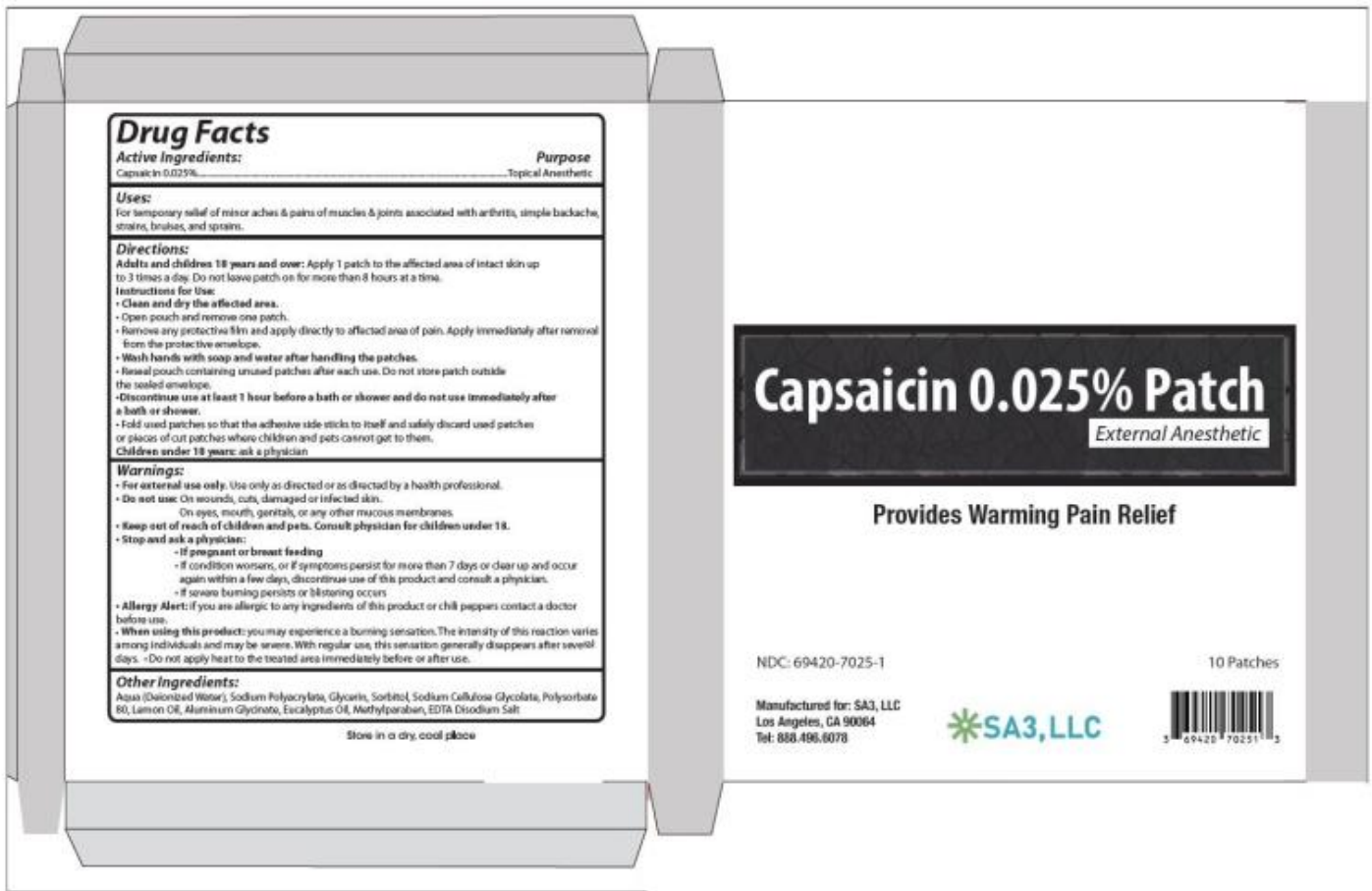
### Capsaicin 0.025% Patch

NDC 69420-7025-1

10 Patches (5 per Resealable Pouch)

SA3, LLC





## CAPSAICIN

capsaicin patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69420-7025
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>LEMON OIL</b> (UNII: I9GR0824LL)	
<b>DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS</b> (UNII: 1K713C615K)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	

<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69420-7025-1	10 in 1 CARTON	06/11/2021	
1		100 g in 1 PATCH; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/11/2021	

**Labeler - SA3, LLC (079627454)**

Revised: 6/2021

SA3, LLC