

**NEURITERX- capsaicin cream**  
**Sempraе Laboratories 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.*

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**Capsaicin**

**Active Ingredient**

Capsaicin 0.05%

**Purpose**

Topical analgesic

**Uses**

For the temporary relief of minor aches and pains of muscles and joints due to

- simple backache
- arthritis
- strains
- sprains

**Warnings**

**For external use only**

**When using this product**

- use only as directed
- do not bandage tightly
- do not use with heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds, damaged, broken or irritated skin
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning sensation occurs, discontinue use immediately
- do not expose the area treated with product to heat or direct sunlight

Stop use and ask a doctor if

- Condition worsens
- Redness is present
- Irritation develops
- Symptoms persist for more than 7 days or symptoms clear up and occur again within a few days

*Keep out of reach of children*

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

**Directions**

**Adults and children over 18 years:**

- Apply to affected area

- Massage into painful area until thoroughly absorbed
- Repeat as necessary, but no more than 3 to 4 times daily

**Children 18 years or younger:** ask a doctor

### Other Information

Store at 20° - 25°C (68° - 77°F)

Do not use if inner container seal is damaged or missing.

### Inactive Ingredients

Almond Oil, Benzyl Alcohol, Benzyl Benzoate, Butylated Hydroxytoluene, Carbomer Copolymer Type B, Cinnamon

Bark Oil, Coriander Oil, Edetate Disodium, Isopropyl Alcohol, L-Arginine HCl, L-Citrulline , Polyoxl 40 Hydrogenated Castor Oil, Propylene Glycol, Sorbitol, Trolamine, Water



capsaicin cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72826-140
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.05 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALMOND OIL (UNII: 66YXD4DKO9)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZYL BENZOATE (UNII: N863NB338G)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
CORIANDER OIL (UNII: 7626GC95E5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
CITRULLINE (UNII: 29VT07BGDA)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72826-140-14	1 in 1 CARTON	11/20/2020	
1		56.7 g in 1 CONTAINER; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	11/20/2020	

**Labeler** - Semprae Laboratories Inc (093739668)

## Establishment

Name	Address	ID/FEI	Business Operations
Topical Pharmaceuticals Inc.		831530683	manufacture(72826-140)

Revised: 11/2020

Sempra Laboratories Inc