

NEURITERX- capsaicin 0.075% cream

Semprae 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.

Semprae Capsaicin

Active Ingredient

Capsaicin 0.075%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- 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

Neuriterx Carton



NEURITERX

capsaicin 0.075% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72826-130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.075 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
ARGININE HYDROCHLORIDE (UNII: F7LTHIE20Y)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZYL BENZOATE (UNII: N863NB338G)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CITRULLINE (UNII: 29VT07BGDA)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
CORIANDER OIL (UNII: 7626GC95E5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
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:72826-130-14	1 in 1 CARTON	12/10/2019	
1		56.7 g in 1 CONTAINER; 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	12/10/2019	

Labeler - Semprae Laboratories Inc (093739668)

Registrant - Semprae Laboratories Inc (093739668)

Establishment

Name	Address	ID/FEI	Business Operations
Topical Pharmaceuticals Inc.		831530683	manufacture(72826-130)

Revised: 12/2019

Semprae Laboratories Inc