

SOOTHANOL X2- capsaicin and menthol solution/ drops
NewMarket Health Products 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.

Soothanol X2

Active Ingredients

Capsaicin 0.20%

Menthol 12%

Purpose

Topical Analgesic

Topical Analgesic

Uses for 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

- avoid contact with eyes or mucus membranes
- do not bandage tightly
- do not apply to wounds or damaged skin

Stop use and ask doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- excessive irritation of skin develops

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

Keep out of reach of children.

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

Directions

- adults and children 12 years of age and older: wash hands and affected area with lukewarm water and apply 2-3 drops with fingertips not more than 3 to 4 times daily
- children under 12 years of age: consult a physician
- do not use otherwise than as directed

Other information

Store in a cool, dry place.

Inactive ingredients

arnica flower, calendula flower, dimethyl sulfoxide (DMSO), d-Limonene oil, emu oil (non-vegetarian),

extra virgin olive oil, ginger root, methylsulfonylmethane (MSM), st. john's wort, wintergreen oil

Questions or comments?

Call (800) 895-2108, Monday through Friday, 8am-8pm EST

www.NorthStarNutritionals.com

North Star

Nutritionals

SOOTHANOL X2

Pain Relieving Drops

Net: 1 Fluid OZ/ 30 ML

SOOTHANOL X2			
capsaicin and menthol solution/ drops			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50972-766
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

1" x 0.5"
Unvarnished Area



SOOTHANOL X2

Pain Relieving Drops

Net: 1 Fluid OZ/30 ML

Do not use if seal around cap is broken or missing.

Manufactured in USA using ingredients of international and domestic origin.

Distributed by NewMarket Health Products, LLC
1125 N Charles St. • Baltimore, MD 21201

To reorder, call: (800) 895-2108
Refill Code: K650T4AA • 650SS02 • LR-T6

Drug Facts (continued)

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Permanent Adhesive Area

Drug Facts

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Menthol 12%.....	Topical Analgesic

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Lift Here for Additional Product Information 

Ingredient Name		Basis of Strength	Strength	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)		CAPSAICIN	2 mg in 1 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	120 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
ARNICA ANGUSTIFOLIA FLOWER (UNII: NG0U89QRD8)				
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)				
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)				
LIMONENE, (+)- (UNII: GFD7C86Q1W)				
EMU OIL (UNII: 344821WD61)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
GINGER (UNII: C5529G5JPQ)				
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)				
ST. JOHN'S WORT (UNII: UFH8805FKA)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50972-766-01	1 in 1 BOX	06/11/2014	
1		28.3 g in 1 BOTTLE, DROPPER; 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	06/11/2014		

Labeler - NewMarket Health Products LLC (055293706)

Establishment

Name	Address	ID/FEI	Business Operations
Vitality Works, Inc.		137752817	manufacture(50972-766)

Revised: 8/2017

NewMarket Health Products LLC