

SNO SWEDISH ARCTIC GEL RELIEF- camphor, menthol gel
Natumin Pharma AB

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.

Drug Facts

Active Ingredients

Camphor 2.2%

Menthol 3.6%

Purpose

Topical Analgesic

Uses

temporarily relieves minor pain associated with

- simple backache
- muscle strains
- sprains
- bruises

Warning

For external use only

When using this product

- use only as directed
- read and follow all directions and warnings on this label
- rare cases of serious burns have been reported with products of this type
- do not bandage tightly or apply local heat (such as heating pads) or medicated patches to the area of use
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged, broken, or irritated skin
- a transient burning sensation may occur upon application but generally disappears in several days

Stop use and ask doctor if

- Condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

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 over 12 years:

apply a thin layer to affected area

massage into painful area until thoroughly absorbed into skin

repeat as necessary, but no more than 3 to 4 times daily, allowing a minimum of 2-3 hours between applications.

After applying, wash hands with soap and water.

Children 12 years or younger: ask a doctor

Other Information

Store at 68-77°F (20-25°C)

Protect from excessive moisture

Inactive Ingredients

ammonium acryloyldimethyltaurate/ VP copolymer

ethylhexylglycerin

glycerin

isostearyl isostearate

PEG-40 hydrogenated castor oil

phenoxyethanol

propylene glycol

sodium hydroxide

water

Principle Display Panel-100g tube carton



SNO SWEDISH ARCTIC GEL RELIEF			
camphor, menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70316-330
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2.2 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	3.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISOSTEARYL ISOSTEARATE (UNII: IV0Z586Z4Y)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70316-330-02	1 in 1 CARTON		
1		100 g in 1 TUBE; 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	01/05/2016	

Labeler - Natumin Pharma AB (426847083)**Registrant** - Natumin Pharma AB (426847083)**Establishment**

Name	Address	ID/FEI	Business Operations
Natumin Pharma AB		426847083	manufacture(70316-330)

Revised: 1/2016

Natumin Pharma AB