SNO SWEDISH ARCTIC GEL SUPPORT- 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 2.8%

Menthol 2.25%

Purpose

Topical Analgesic

Uses

temporarily relieves minor pain associated with

- simple backache
- muscle strains
- sprains
- bruises

Warnings

For external use only

When using this product us 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 applicaiton bu generally disappears in several days

Stop use and ask doctor if

Condition worsens

Redness is present

Irritation develops

Sympotms 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 breastfeeding

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 under, ask a doctor

Other Information

Store at 68-77°F (20-25°C)

Protect from excessive moisture

Inactive Ingredients

ammonium acryloyldimethyltaurate/ VP copolymer

arnica montana flower extract

ethylhexylglycerin

glycerin

helianthus annuus (sunflower) seed oil

isostearyl isostearate

PEG-40 hydrogenated castor oil

phenoxyethanol

propylene glycol

sodium hydroxide

water

Principle Display Panel- 100g Tube Carton

SNO SWEDISH ARCTIC GEL SUPPORT

camphor, menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70316-320
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2.8 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	2.25 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ISOSTEARYL ISOSTEARATE (UNII: IV0Z586Z4Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70316-320-02	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	01/02/2016	

Labeler - Natumin Pharma AB (426847083)

Registrant - Natumin Pharma AB (426847083)

Establishment

Name	Address	ID/FEI	Business Operations
Natumin Pharma AB		426847083	manufacture(70316-320)