SOFSKIN ICE ANALGESIC- menthol gel Nova Petroleum & Chemicals Corporation

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.

Ice Analgesic Gel

Label for

NOVA PETROLEUM & CHEMICALS CORP.

Ice Analgesic Gel

Drug Facts:

Active Ingredients:

Menthol 1%

Purpose:

Topical Analgesic

Uses

Provide temporary relief of minor aches and pains in muscles and joints associated with samples backache, strains, sprains, arthritis sports injuries.

Warnings

For external use only-Not for internal use.

Use only as directed. Avoid contact with eyes or mucous membranes. Do not apply to wounds or damaged skin. Make sure skin is clean and free from any creams, ointments, sprays or liniment. Do not bandage.

Do not use

with heating pads or heating devices.

If condition worsens or symptoms persist for more than 7 days or if symptoms disappear and occur again within a few days, discontinue use and consult a physician. If you have sensitive skin, consult a physician before use. If skin irritation develops, discontinue use and consult a physician. If you are pregnant or nursing a baby consults your doctor before use. Do not use, store, pour or spill near heat or open flames. Store in a cool, dry place and keep lid tightly closed.

Directions

Clean skin of all other lotions, creams, ointments, liniment or sprays, Apply liberally to affected area and massage until gel is absorbed into skin. Do not apply more than 3 or 4 times daily. No protective cover needed. Do not apply to children under 2 years of age.

Made in India

Imported by:

Nova Petroleum & Chemicals Corp.

3 Roethal Drive Suite 1 D

Hopewell Junction, NY 12533

www.novawax.com

Distributed by:

Vini Health and Beauty Products Inc.

3 Roethal Drive Suite 1 D

Hopewell Junction, NY 12533

Principal Display Panel

Sofskin Ice analgesic gel Fast, temporary relief from muscle aches and pains Net Wt. 7 Oz. (200 g)



SOFSKIN ICE ANALGESIC

menthol gel **Product Information** HUMAN OTC DRUG NDC:52069-104 **Product Type** Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient** Name **Basis of Strength** Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 2.27 g in 227 g Packaging # **Item Code Package Description Marketing Start Date Marketing End Date 1** NDC:52069-104-07 227 g in 1 JAR

Marketing Information					
Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part341	03/10/2010			

Labeler - Nova Petroleum & Chemicals Corporation (831871731)

Establishment					
Name	Address	ID/FEI	Business Operations		
Kim Chemicals LTD		650470164	MANUFACTURE		

Revised: 3/2010

Nova Petroleum & Chemicals Corporation