IRXSINOREL- camphor (synthetic) and menthol, unspecified form liniment ActivPower 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.

IRxSinorel

Drug Facts

Active Ingredient	Purpose
Camphor 10%	Topical analgesic
Menthol 10%	Topical analgesic

Uses

For application on to intact unbroken skin to help achieve the temporary relief of sinus pain.

Warnings

For external use only.

When using this product

Avoid contact with eyes and mucous membranes, wounds, damaged or irritated skin. Do not bandage or cover with wrap or apply any heat or heating pad to area after use. Wash hands with soap and water after using this product.

Stop use and Ask doctor if

Condition worsens. Severe skin irritation occurs. Pain persists for more than 4 days. Pain clears up and then recurs after a few days.

If pregnant or breast-feeding

This product has not been tested in pregnant or breast-feeding women. Consult the advice of your doctor before using this product in these situations.

Keep out of reach of children

Not recommended for use in children 12 years old or younger. If swallowed, get medical help or contact Poison Control immediately. If exposure to eyes, then wash copiously with cold water and consult a doctor. Components are not certified to be free of nut allergens. Do not use if allergic to nuts or peanuts or if allergic to any of the components without testing. Use on a small area for the first time. If rash or itching develops then discontinue use. If symptoms persist then consult a medical professional. If the intended area of application or joint is hot, red, bruised or swollen then do not apply this liniment and immediately seek professional medical help.

Inactive Ingredients

Eucalyptus Oil; Castor Oil;

Directions for Use

For Topical use. Apply 2ml-3ml into forehead and over cheek sinuses and rub in gently until it vanishes.

May apply up to twice daily. Do not exceed recommended frequency of application. Do not apply heat after application. This product will produce a soothing relief and sensation of cooling in the area of application.

Questions/Comments

703-404-5905

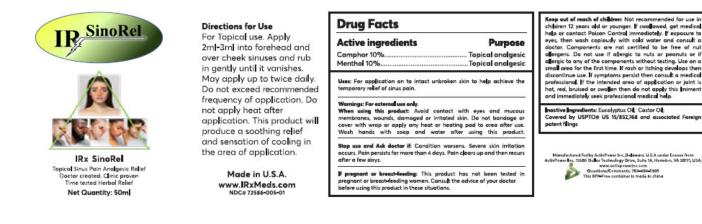
Manufactured for/by ActivPower Inc., Delaware, U.S.A under license from ActivPower Inc. 13505 Dulles Technology Drive, Suite 1A, Herndon, VA 20171, USA;

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Label

IRx SinoRel

Topical Sinus Pain Analgesic Relief Doctor created. Clinic proven Time tested Herbal Relief

Net Quantity: 50ml



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IRXSINOREL

camphor (synthetic) and menthol, unspecified form liniment

Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72586-005				
Route of Administration	TOPICAL						

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	100 mg in 1 mL				
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	100 mg in 1 mL				

Ingredient Name					Strength			
E	UCALYPTUS OIL (UNII: 2R04	ONI662)					
C	ASTOR OIL (UNII:	D5340 Y2I9	G)					
Packaging								
#	Item Code		Package Description	Marketing Start Date	Marketing End Date			
1	NDC:72586-005- 01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		07/01/2020				
Marketing Information								
Marketing Category		gory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
0	TC MONOGRAPH N	OT FINAL	part348	07/01/2020				

Labeler - ActivPower Inc. (116767431)

Revised: 7/2020

ActivPower Inc.