

IRXAMIGRA- camphor (synthetic), menthol, unspecified form, and capsaicin 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.

IRxAmigra

Drug Facts

Active Ingredient	Purpose
Camphor 10 %	Topical analgesic
Menthol 5%	Topical analgesic
Capsaicin 0.075%	Topical analgesic

Uses

For application on to intact unbroken skin to help achieve the temporary relief of minor head and neck aches

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; Clove Oil; Frankincense Oil; Oleoresins of Cinnamon and Black Pepper; Curcumin; Ethanol; Castor Oil; Petrolatum; Sorbitan stearate.

Directions for Use

For Topical use. Apply 2ml-3ml into forehead, temples or neck 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 heat and warmth 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 Amigra

Topical Head and Neck Muscle Pain Relief

Doctor created. Clinic proven

Time tested Herbal Relief

Net Quantity: 50ml



IRx Amigra

Topical Head and Neck Muscle Pain Relief
 Doctor created. Clinic proven
 Time tested Herbal Relief
 Net Quantity: 50ml

Directions for Use

For Topical use. Apply 2ml-3ml into forehead, temples or neck 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 heat and warmth in the area of application.

Made in U.S.A.
www.IRxMeds.com
 NDC# 72586-004-01

Drug Facts

Active ingredients	Purpose
Camphor 10%.....	Topical analgesic
Menthol 5%.....	Topical analgesic
Capsaicin 0.075%.....	Topical analgesic

Uses: For application on to intact unbroken skin to help achieve the temporary relief of minor head and neck aches

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; Clove Oil; Frankincense Oil; Oleoresins of Cinnamon and Black Pepper; Curcumin; Ethanol; Castor Oil; Petrolatum; Sorbitan stearate.
 Covered by USPTO# US 15/852,768 and associated Foreign patent filings

Manufactured for/by ActivPower Inc., Delaware, U.S.A under license from ActivPower Inc. 13505 Dulles Technology Drive, Suite 1A, Herndon, VA 20171, USA;
 www.activpowerinc.com
 Questions/Comments: 703-404-5905
 This BPA-Free container is made in china

IRXAMIGRA			
camphor (synthetic), menthol, unspecified form, and capsaicin liniment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72586-004
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	50 mg in 1 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CLOVE OIL (UNII: 578389D6D0)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
CURCUMIN (UNII: IT942ZTH98)	
BLACK PEPPER OIL (UNII: U17J84S19Z)	
PETROLATUM (UNII: 4T6H12BN9U)	
CASTOR OIL (UNII: D5340Y2I9G)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72586-004-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	07/01/2020	

Labeler - ActivPower Inc. (116767431)