# 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.

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#### 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





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

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Active ingredients

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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/Convments: 703–104-5905 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:7258	6-004
Route of Administration	TOPICAL			
<b>Active Ingredient/Active Moi</b>	ety			
Ingredient Name		Basi	is of Strength	Strength

CAPSAICIN (UNIE S07O44RIZM) (CAPSAICIN - UNIES07O44RIZM)       CAPSAICIN       0.75 mg in 1 mL         0.75 mg in 1 mL         Inactive Ingredients         Ingredient Name       0.75 mg in 1 mL         Ingredient Name       Strength         EUCALYPTUS OIL (UNIE 2R040NI662)       Strength         CLO VE OIL (UNIE 578389D6D0)       Strength         FRANKINCENSE OIL (UNIE 672YAST02K)       Strength         CINNAMON OIL (UNIE 672YAST02K)       Strength         CURCUMIN (UNIE 1594227H98)       Strength         BLACK PEPPER OIL (UNIE 107J84S19Z)       Strength         STOR OIL (UNIE 4T6H12BN9 U)       CASTOR OIL (UNIE 4T6H12BN9 U)         CASTOR OIL (UNIE 105340 Y219 G)       STOR OIL (UNIE NVZ410H58X)         STOR OIL (UNIE 105340 Y219 G)       STOR OIL (UNIE 105340 Y219 G)         STOR OIL (UNIE 105340 Y219 G)       STOR OIL (UNIE 105340 Y219 G)         STOR OIL (UNIE 105340 Y219 G)       STOR OIL (UNIE 105340 Y219 G)         STOR OIL (UNIE 105340 Y219 G)       STOR OIL (UNIE 105340 Y219 G)         STOR OIL (UNIE 10 STOR OIL (UNIE 10 STOR OIL 10 STOR OIL 1	<b>CAMPHOR (SYNTH</b> UNII:5TJD82A1ET)	ETIC) (UNI	I: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) -	CAMPHOR (SYNT	CAMPHOR (SYNTHETIC)		
CAPSAICIN (UNIE 30/044R12M) (CAPSAICIN - UNIES0/044R12M)       CAPSAICIN       in 1 mL         Inactive Ingredients       Ingredient Name       Strength         EUCAL YPTUS OIL (UNIE: 2R040N1662)       50 Krength       Strength         CLOVE OIL (UNIE: 578389D6D0)       FRANKINCENSE OIL (UNIE: 672Y45702K)       Image: Capsaicing Caps	MENTHOL, UNSPEC UNII:L7T10EIP3A)	CIFIED FOI	RM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FO				
Ingredient Name         Strength           EUCAL YPTUS OIL (UNIE 2R040N1662)         Gite Colspan="2">Strength           CLOVE OIL (UNIE 57838906D0)         Gite Colspan="2">Strength           FRANKINCENSE OIL (UNIE 57838906D0)         Gite Colspan="2">Strength           FRANKINCENSE OIL (UNIE 57702K)         Gite Colspan="2">Gite Colspan="2">Strength           COLSCUMIN (UNIE E5GY46 YCZ)         Gite Colspan="2">Gite Colspan="2">Gite Colspan="2">Gite Colspan="2">Gite Colspan="2">Strength           COLSCUMIN (UNIE 1942ZTH98)         Gite Colspan="2">Gite Colspan= 2"           FIRE Colspan= Colspan= 2"         Gite Colspan="2"           FIRE Colspan= Colspan= 2"         Gite Colspan= 2"         Marketing Start         Marketing Colspan= 2"         Marketing Colspan= 2"         Gite Colspan= 2"         Gite Colspan= 2"         Marketing Colspan= 2"         Gite Colspan= 2"         Marketing Colspan= 2" <td cols<="" td=""><td>CAPSAICIN (UNII: SO</td><td>)7O44R1ZM</td><td>ſ) (CAPSAICIN - UNII:S07O44R1ZM)</td><td>CAPSAICIN</td><td></td><td>0</td></td>	<td>CAPSAICIN (UNII: SO</td> <td>)7O44R1ZM</td> <td>ſ) (CAPSAICIN - UNII:S07O44R1ZM)</td> <td>CAPSAICIN</td> <td></td> <td>0</td>	CAPSAICIN (UNII: SO	)7O44R1ZM	ſ) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN		0
Ingredient Name         Strength           EUCAL YPTUS OIL (UNIE 2R040N1662)         Gite Colspan="2">Strength           CLOVE OIL (UNIE 57838906D0)         Gite Colspan="2">Strength           FRANKINCENSE OIL (UNIE 57838906D0)         Gite Colspan="2">Strength           FRANKINCENSE OIL (UNIE 57702K)         Gite Colspan="2">Gite Colspan="2">Strength           COLSCUMIN (UNIE E5GY46 YCZ)         Gite Colspan="2">Gite Colspan="2">Gite Colspan="2">Gite Colspan="2">Gite Colspan="2">Strength           COLSCUMIN (UNIE 1942ZTH98)         Gite Colspan="2">Gite Colspan= 2"           FIRE Colspan= Colspan= 2"         Gite Colspan="2"           FIRE Colspan= Colspan= 2"         Gite Colspan= 2"         Marketing Start         Marketing Colspan= 2"         Marketing Colspan= 2"         Gite Colspan= 2"         Gite Colspan= 2"         Marketing Colspan= 2"         Gite Colspan= 2"         Marketing Colspan= 2" <td cols<="" td=""><td></td><td></td><td></td><td></td><td></td><td></td></td>	<td></td> <td></td> <td></td> <td></td> <td></td> <td></td>						
EUCAL YPTUS OIL (UNIE 2R040/NI662)       Image: Colspan="2">Image: Colspan="2" Image: Colspan="2">Image: Colspan="2" Image: Colspan=	Inactive Ingredi	ients					
CL VE OIL (UNI: 578389D6D0)       (Marketing Start Day         FRANKINCENSE OIL (UNI: 577378)       (Marketing Start Day         FRANKINCENSE OIL (UNI: 55GY4/5725)       (Marketing End Day         CURCUMIN (UNI: 1794227198)       (UNI: 0171845192)         BLACK PEPER OIL (UNI: 4761128)       (UNI: 4761128)         PETROLATUM (UNI: 4761128)       (UNI: 05340 Y2)         CASTOR OIL (UNI: 50340 Y2)       (UNI: 000000000000000000000000000000000000			Ingredient Name		Strength		
FRANKINCENSE OIL (UNII: 67ZYA5T02K)   CINAMON OIL (UNII: E5GY46 YCZ)   CURCUMIN (UNII: E5GY46 YCZ)   CURCUMIN (UNII: E5GY46 YCZ)   CURCUMIN (UNII: E5GY46 YCZ)   CURCUMIN (UNII: D5340 Y219G)   FTROLATUM (UNII: 4T6H12BN9U)   CASTOR OIL (UNII: 50340 Y219G)   CASTOR OIL (UNII: D5340 Y219G)   CASTOR OIL (UNII: NVZ410 H58 X)   PETROLATUM MONOSTEARATE (UNII: NVZ410 H58 X)   Packaging   Marketing Start   Marketing Start   Marketing Start   Marketing Category   Application Number or Monograph Citation   Marketing Start Date	EUCALYPTUS OIL (	UNII: 2R04	ONI662)				
Image: Second	CLOVE OIL (UNII: 5	78389D6D	0)				
CURCUMIN (UNI: IT942ZTH98)       indication Number or Monograph Citation       Marketing Start Date       Marketing Start Date         BLACK PEPPER OIL (UNI: UTJ84S19Z)       indication Number or Monograph Citation       Marketing Start Date       Marketing Cate gory	FRANKINCENSE O I	L (UNII: 672	ZYA5T02K)				
BACK PEPER OIL (UNI: U17J84S19Z)   I (UNI: U17J84S19Z)   I (UNI: U17J84S19Z)   I (UNI: D5340 Y219G)   SORBITAN MONOSTEARATE (UNII: NVZ410H58X) I tem Code   Package Description   Marketing Start Marketing End   Date Date   1 NDC:72586-004- 01 50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 07/01/2020   Ketting Information   Marketing Category   Application Number or Monograph Citation Marketing Start Date Marketing End Date	CINNAMON OIL (UN	NII: E5GY4I	5YCZ)				
PETRO LATUM (UNI: 4T6H12BNU)   CASTOR OIL (UNI: 5340 Y219G)   SORBITAN MONOSTEARATE (UNI: NVZ4I0H58X)     Package Description Marketing Start Date   Marketing Start Date   NDC:72586-004- 01   50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product   Other Start Date   Marketing Information   Marketing Category   Application Number or Monograph Citation   Marketing Start Date   Marketing Start Date Marketing End Date Marketing End Date Marketing Category	CURCUMIN (UNII: IT	942ZTH98)	)				
STOR OIL (UNII: D5340 Y2 I) G)   STOR OIL (UNII: D5340 Y2 I) G)   STOR OIL (UNII: D5340 Y2 I) G)   STOR OND STEARATE (UNII: NVZ410H58 X)     I   I   I   I   NDC:72586-004-   01   STIL I I BOTTLE, PLASTIC; Type 0: Not a Combination   Product      Induct State	BLACK PEPPER OII	L (UNII: U17	7J84S19Z)				
BITAN MONOSTARATE (UNII: NVZ410H58X)     Variable     Variabl	PETROLATUM (UNI	II: 4T6 H12B	N9 U)				
Marketing Start Date         Marketing Cate       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       07/0 1/2020       07/0 1/2020	CASTOR OIL (UNII:	D5340 Y2I9	G)				
#       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       07/01/2020         Varketing Interstation         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date	SORBITAN MONOS	TEARATE	(UNII: NVZ4I0 H58 X)				
#       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       07/01/2020         Varketing Interstation         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date							
#       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       07/01/2020         Varketing Interstation         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date							
#     Item Code     Package Description     Date     Date       1     NDC:72586-004- 01     50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product     07/01/2020     07/01/2020	Packaging						
Marketing Information         Marketing Category       Application Number or Monograph Citation	# Item Code		Package Description	-		•	
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date			BOTTLE, PLASTIC; Type 0: Not a Combination	07/01/2020			
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date							
	Marketing In	format	ion				
OTC MONOGRAPH NOT FINAL part348 07/01/2020	Marketing Cate	egory	Application Number or Monograph Citation	Marketing Start Date	Market	ng End Dat	
	OTC MONOGRAPH N	OT FINAL	part348 (	07/01/2020			

Labeler - ActivPower Inc. (116767431)

Revised: 7/2020

ActivPower Inc.