# DENDRACIN NEURODENDRAXCIN - methyl salicylate, menthol and capsaicin lotion H.J. Harkins Company, 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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### Dendracin Neurodendraxcin®, Topical Pain Relief Lotion

#### **Active ingredients**

Methyl Salicylate 30% Menthol 10% Capsaicin 0.025%

#### Purpose

**Topical Analgesic** 

#### Uses:

For temporary relief of mild pain due to muscular strain, arthritis, and simple back pain. Does not cure any disease.

#### Warnings:

For external use only. Do not use in eyes, mouth, on mucous membranes, or genitals. Do not tightly bandage. Do not use with heating pad. Do not use with other topical pain products.

#### Keep away from children.

#### **Directions:**

Use only as directed. Shake before each use. Prior to first use, rub small amount to check for sensitivity. Gently rub over painful areas. Dry before contact with clothes or bedding to avoid staining. Wash hands after use. Do not use more than 4 times daily or if pregnant or nursing. If swallowed, call poison control. If placed into eyes, rinse with cold water and call a doctor.

#### Do Not Use:

On cuts or infected skin, on children less than 12 years old, in large amounts, especially over raw or blistered skin, if allergic to any ingredients, PABA, aspirin products, or sulfa.

#### Store below 90°F/32°C.

#### Stop Use and Ask a Physician:

For severe undiagnosed pain. If pain worsens or persist for more than 7 days. If pain clears up and then recurs in a few days. If itching or rash occurs.

#### Inactive ingredients:

Water, benzocaine, glyceryl stearate, PEG 100 stearate, stearic acid, cetyl alcohol, propylene glycol, dimethyl sulfoxide, triethanolamine, poloxamer 407, aloe barbadensis gel, borage oil, ammonium acryloyldimethyltaurate, zingiber officinale root extract, methylparaben, propylparaben, soya lecithin, DMDM hydantoin, sodium stearoyl glutamate.

Manufactured for Physicians' Science and Nature, Inc. 220 Newport Center Drive 11-634, Newport Beach, CA 92660 Relabeled by: H.J. Harkins Company, Inc. Nipomo, CA 93444 Made in the USA

#### **Principal Display Panel**

**Patent Pending** 

Physicians' Science and Nature Inc. Dendracin <u>Neurodendraxcin®</u> *New Formula Professional Formula Topical Pain Relief Lotion Deep Penetrating Action* 120 ml (4 fl oz) NDC 27495-014-04

52959-930-12 RX Only:	#XXXXXXXX #X	XX CAUTION other than without a OUT O Ri degrees F	I: Federal law PROHIBITS the tra in the person to whom prescribed a prescription unless OTC. See out EACH OF CHILDREN. Store in a	nsfer of this drug to anyone and prohibits dispensing sert for add'1 RX info KEEP cool dry place 68 to 77
DENDRACIN LOTION Lot #: DNC02ZU Mfg: PHYSICIANS		degrees r	DENDRACIN LOTIC 52959-930-12	N Qty 120ml ot DNC02ZU 27495-014-04
Exp: 03/11Compare to:Mfg NewportMfg. NDC: 27495-014-04Loc.: Beach, CAPill ID: Topical lotion			DENDRACIN LOTIC 52959-930-12 03/11 Lo	Qty 120ml
Take as directed by your Doctor or See outsert for usual dosage information			DENDRACIN LOTIC 52959-930-12 03/11 L	Qty 120ml
Take as directed by your Doctor of See outsert for usual dosage infor		0 - 5 6 7 7 2	DENDRACIN LOTIC 52959-930-12 03/11 Lo	Qty 120ml
			Repack: HJ Harkins Co., Inc. Dispense in tight, child & ligh	Nipomo., CA 93444 t-resistant container per USP

#### 4 oz Label

## DENDRACIN NEURODENDRAXCIN

methyl salicylate, menthol and	nethyl salicylate, menthol and capsaicin lotion						
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source	e) NDC:5295	59-930(ND	C:27495-014)		
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingredient Name				rength	Strength		
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) METHYL SALICYLATE				CYLATE 1	8 mL in 60 mL		
MENTHOL (UNII: L7T10EIP3A) (I	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL				mL in 60 mL		
CAPSAICIN (UNII: S07O44R1ZM)	) (CAPSAICIN - UNII:S07O44R1	ZM)	CAPSAICIN	0	.015 mL in 60 mI		
Inactive Ingredients							
	Ingredient Na	me			Strength		
WATER (UNII: 059QF0KO0R)							
BENZOCAINE (UNII: U3RS Y48 JV	W5)						
GLYCERYL MONOSTEARATE	(UNII: 230 O U9 XXE4)						
PEG-100 STEARATE (UNII: YD0	1N1999R)						
STEARIC ACID (UNII: 4ELV7Z65	JAP)						
PROPYLENE GLYCOL (UNII: 61	DC9Q167V3)						
CETYL ALCOHOL (UNII: 936JS	T6JCN)						
DIMETHYL SULFOXIDE (UNII: Y	YO W8 V9 6 9 8 H)						
POLOXAMER 407 (UNII: TUF2IN	VW3M2)						
ALOE VERA LEAF (UNII: ZY81Z	83H0X)						
BORAGE OIL (UNII: F8XAG1755	iS)						
AMMONIO METHACRYLATE C	OPOLYMER TYPE A (UNII: 8	GQS4E66YY)					
GINGER (UNII: C5529G5JPQ)							
LECITHIN, SOYBEAN (UNII: 1DI	56QDM62)						
METHYLPARABEN (UNII: A218 C	27HI9T)						
PROPYLPARABEN (UNII: Z8IX2	SC10H)						
DMDM HYDANTO IN (UNII: BYRG	)546TOW)						
SODIUM STEAROYL GLUTAM	<b>ATE</b> (UNII: 65A9F4P024)						
TROLAMINE (UNII: 903K93S3T	'K)						
Packaging							
# Item Code	Package Description	Marketing Sta	nrt Date	Marketi	ng End Date		
<b>1</b> NDC:52959-930-12 50	in 1 CARTON						
<b>1</b> 60	mL in 1 BOTTLE						
<b>2</b> NDC:52959-930-60 50	in 1 CARTON						
2 120	) mL in 1 BOTTLE						
Marketing Informati	on						
•	plication Number or Monog	ranh Citation Ma	rketing Start D	ate Mar	keting End Date		
Apple and	and the second	aph chutton Mid	The ding of the t	ute mul	in the Line Date		

07/22/2011

# Labeler - H.J. Harkins Company, Inc. (147681894)

Registrant - Physicians Science & Nature Inc. (012485755)

Establishment							
Name	Address	ID/FEI	Business Operations				
Westwood Laboratories		069926483	MANUFACTURE				

Revised: 12/2011

H.J. Harkins Company, Inc.