DENDRACIN NEURODENDRAXCIN- methyl salicylate, menthol and capsaicin lotion Preferred Pharmaceuticals, 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.

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

Made in the USA

Patent Pending

Relabeled by Preferred Pharmaceuticals, Inc.

Principal Display Panel

Physicians' Science and Nature Inc.

Dendracin

<u>Neurodendraxcin</u>®

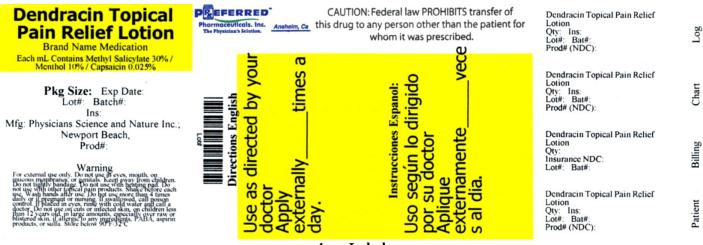
New Formula

Professional Formula

Topical Pain Relief Lotion

Deep Penetrating Action

120 ml (4 fl oz)



4 oz Label

4 oz Label

DENDRACIN NEURODENDRAXCIN

methyl salicylate, menthol and capsaicin lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-9294(NDC:27495-014)
Route of Administration	TOPICAL		

Active Ingredient/A	Active Moiety						
	Ingredient Name	Basis of Strength	Strength				
METHYL SALICYLATE	(UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414P2	Z4LPZ) METHYL SALICYLATE	18 mg in 60 mg				
MENTHOL (UNII: L7T10E	EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 mg in 60 mg				
CAPSAICIN (UNII: S0704	44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.015 mg in 60 mg				
Inactive Ingredient	S						
	Ingredient Name		Strength				
WATER (UNII: 059QF0K	DOR)						
BENZOCAINE (UNII: U3F	RS Y48 JW5)						
GLYCERYL MONOSTE	ARATE (UNII: 230OU9XXE4)						
PEG-100 STEARATE (UNII: YD01N1999R)							
STEARIC ACID (UNII: 4ELV7Z65AP)							
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
CETYL ALCOHOL (UNII: 936JST6JCN)							
DIMETHYL SULFOXIDE	E (UNII: YOW8V9698H)						
POLOXAMER 407 (UNII	: TUF2IVW3M2)						
ALOE VERA LEAF (UNII	: ZY8 1Z8 3H0 X)						
BORAGE OIL (UNII: F8 X	AG1755S)						
AMMONIO METHACRY	LATE COPOLYMER TYPE A (UNII: 8GQS4E66YY)						
GINGER (UNII: C5529G5J	IPQ)						
LECITHIN, SOYBEAN (U	JNII: 1DI56QDM62)						
METHYLPARABEN (UNII: A218 C7HI9T)							
PROPYLPARABEN (UNI	I: Z8IX2SC1OH)						
DMDM HYDANTO IN (UNII: BYR0546 TOW)							
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)							
TROLAMINE (UNII: 903K93S3TK)							
Packaging							
# Item Code	Package Description	Marketing Start Date M	arketing End Dat				
1 NDC:68788-9294-1 12	0 mg in 1 BOTTLE; Type 0: Not a Combination Produc	ct					
Marketing Infor	mation						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date M	arketing End Dat				
OTC monograph not final	part348	12/02/2014					
	r						

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

Establishment

Name

Address

Busi

ID/FEI

Business Operations

Preferred Pharmaceuticals, Inc.	79	91119022	RELABEL(68788-9294)

Revised: 2/2015

Preferred Pharmaceuticals, Inc.