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.

Keep away from children and pets.

If swallowed get medical help or contact a Poison Control Center right away.

WARNINGS:

For external use only. Do not use in eyes, mouth, on mucous membranes, or genitals. Do not allow treated skin to contact infants or pets. Do not tightly bandage. Do not use with heating pad. Do not use with other topical pain products. May stain furniture, clothing or bedding.

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 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:

Aloe Barbadensis (Aloe Vera) Leaf Juice, Ammonium Acryloyldimethyltaurate/VP Copolymer, Benzocaine, Borago Officinalis Seed Oil (Borage Oil), Cetyl Alcohol, Dimethyl Sulfoxide, DMDM Hydantoin, Glyceryl Stearate, Methylparaben, PEG 100 Stearate, Poloxamer 407, Propylene Glycol, Propylparaben, Lecithin (Soy), Stearic Acid, Sodium Stearoyl Glucamate, Triethanolamine, Water, Officinale Root Extract.

Manufactured for Physician's Science and Nature Inc.

220 Newport Center Drive 11-634, Newport Beach, CA 92660

Principal Display Panel

Physician's Science and Nature Inc.

Relabeled by Preferred Pharmaceuticals, Inc.

DENDRACIN

<u>Neurodendraxcin</u>®

Professional Formula

Dermatologically Tested

Hypoallergenic

Topical Pain Relief Lotion

Deep Penetrating Action

NDC 68788-7696

Dendracin Topical Pain Relief Lotion	Pharmaceuticals, Inc.	CAUTION: Federal law PROHIBITS transfer of this drug to any person other thean the patient for whom it was prescribed	Dendracin Topical Pain Relief Lotion Qty: Ins: Lot#: Bat#:	Log
Brand Name Medication Each mL Contains Methyl Salicylate 30% / Capsaicin 0.025% / Menthol 10%topical analgesic Pkg Size: Exp Date: Lot#: Batch#:	Vour tim	Espanol: Igido Vece	Prod# (NDC): Dendracin Topical Pain Relief Lotion Qty: Ins: Lot#: Bat#: Prod# (NDC):	Chart
Ins: Mfg: Physicians Science and Nature Inc.; Newport Beach, Prod#: Warning For external use only. Do not use in eves, mouth, on	rections Englected by	cciones tor nte	Dendracin Topical Pain Relief Lotion Qty: Insurance NDC: Lot#: Bat#:	Billing
For external use only. Do not use in eyes, mouth on minous in Do not respectively and the second second page to the second second second second second page to not use with other torofcal pain products. Shake before sach use, Wath hands after use. Do not use pare of the second second second second second second second while the shale of the second second second second while the second second second second second second while the second second second second second second while the second s	Di Use as dir doctor Apply exte es a day.	Instru Uso según por su doc Aplique extername s al dia.	Dendracin Topical Pain Relief Lotion Qty: Ins: Lot#: Bat#: Prod# (NDC):	Patient

120 ml (4 fl oz)

DENDRACIN NEURO					
methyl salicylate, menthol and	a capsaicin lotion				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7696(NDC	·27495-014)	
Route of Administration	TOPICAL		112010070070000		
Nouce of Administration					
Active Ingradient/Active	Majatu				
Active Ingredient/Active	-			.	
Ingr	edient Name		Basis of Strength	Strength 18 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) METHYL SALICYLATE					
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED MENTHOL, UNSPECIFIED FORM UNSPECIFIED FORM					
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN	0.015 g in 60 mL			
Inactive Ingredients					
	Ingredient N	ame		Strength	
WATER (UNII: 059QF0K00R)					
BENZOCAINE (UNII: U3RSY48JW5)					
GLYCERYL MONOSTEARATE (UN	II: 230OU9XXE4)				
PEG-100 STEARATE (UNII: YD01N1999R)					
STEARIC ACID (UNII: 4ELV7Z65AP)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
CETYL ALCOHOL (UNII: 936JST6JCN)					
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)					
POLOXAMER 407 (UNII: TUF2IVW3M2)					
ALOE VERA LEAF (UNII: ZY81Z83	H0X)				
BORAGE SEED OIL (UNII: F8XAG1	755S)				
		NII: 8GQS4E66YY)			

GI	NGER (UNII: C552	29G5JPQ)				
LE	CITHIN, SOYBE	AN (UNII: 1DI56QDM62)				
M	ETHYLPARABEN	(UNII: A2I8C7HI9T)				
PF	ROPYLPARABEN	(UNII: Z8IX2SC10H)				
DI	MDM HYDANTOI	N (UNII: BYR0546TOW)				
SC	DDIUM STEARO	(L GLUTAMATE (UNII: 65A9F4P024)				
TF	ROLAMINE (UNII:	9O3K93S3TK)				
Packaging						
- '	ackaging					
	ackaging Item Code	Package Description	Marketing Start Date	Marketing End Date		
		Package Description 60 mL in 1 BOTTLE; Type 0: Not a Combination Product	-	-		
#	Item Code	60 mL in 1 BOTTLE; Type 0: Not a Combination	Date	-		
# 1	Item Code NDC:68788- 7696-6 NDC:68788-	60 mL in 1 BOTTLE; Type 0: Not a Combination Product 120 mL in 1 BOTTLE; Type 0: Not a Combination	Date 04/01/2020	-		
# 1	Item Code NDC:68788- 7696-6 NDC:68788-	60 mL in 1 BOTTLE; Type 0: Not a Combination Product 120 mL in 1 BOTTLE; Type 0: Not a Combination	Date 04/01/2020	-		
# 1 2	Item Code NDC:68788- 7696-6 NDC:68788- 7696-1	60 mL in 1 BOTTLE; Type 0: Not a Combination Product 120 mL in 1 BOTTLE; Type 0: Not a Combination	Date 04/01/2020	-		

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2020	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	RELABEL(68788-7696)

Revised: 5/2023

Preferred Pharmaceuticals, Inc.