

DENDRACIN NEURODENDRAXCIN- methyl salicylate, menthol and capsaicin lotion
Dispensing Solutions, 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 persists 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 stearyl glutamate.

Manufactured for Physicians' Science and Nature, Inc.

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

Made in the USA

Patent Pending

Principal Display Panel

Physicians' Science and Nature Inc.

Dendracin

Neurodendraxcin®

New Formula

Professional Formula

Topical Pain Relief Lotion

Deep Penetrating Action

120 ml (4 fl oz)

NDC 68258-2997-09

<p>BULK SOURCE DATA MFD. FOR: PHYSICIAN'S SCIENCE AND NATURE INC. NEWPORT BEACH, CA 92660</p> <p>PRODUCT ID: WHITE ROUND BOTTLE WHITE / TAN / YELLOW / BLACK / RED LABEL PRINTED NDC 27495-014-04</p> <p>BULK SOURCE NDC: 27495-0014-04 MFR. LOT: XXXXXX PEDIGREE #: 4005 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p> 	 <p>DENDRACIN 120 ml TOPICAL LOTION NDC 68258-2997-09 PRODUCT # 2D0694</p> <p>ACTIVE INGREDIENTS: METHYL SALICYLATE 30% MENTHOL 10% CAPSAICIN 0.025% (PURPOSE: TOPICAL ANALGESIC)</p> <p>DO NOT USE WITH OTHER TOPICAL PAIN PRODUCTS. SHAKE BEFORE EACH USE.</p> <p>LOT# SAMPLE EXP: 00-00 Rx # 25189222</p>	<p>WARNING: KEEP OUT OF CHILDREN'S REACH STORE BELOW 90° F. SEE USP.</p> <p>2D0694 NDC 68258-2997-09 DENDRACIN 120 ml TOPICAL LOTION LOT # SAMPLE EXP: 00-00 MN 27495-0014-04 RX# 25189222</p> <p>2D0694 NDC 68258-2997-09 DENDRACIN 120 ml TOPICAL LOTION LOT # SAMPLE EXP: 00-00 MN 27495-0014-04 RX# 25189222</p> <p>2D0694 NDC 68258-2997-09 DENDRACIN 120 ml TOPICAL LOTION LOT # SAMPLE EXP: 00-00 MN 27495-0014-04 RX# 25189222</p>  <p>Packaged Exclusively By: DISPENSING SOLUTIONS Inc. Santa Ana, CA 92704</p>
<p>GENTLY MASSAGE INTO AFFECTED AREA _____ TIMES A DAY AS DIRECTED. FOR EXTERNAL USE ONLY. DO NOT USE IN EYES, MOUTH, ON MUCOUS MEMBRANES, OR GENITALS. DO NOT USE WITH HEATING PAD. DO NOT TIGHTLY BANDAGE.</p>	<p>Rev. Date: 09/11</p>	

DENDRACIN NEURODENDRAXCIN

methyl salicylate, menthol and capsaicin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68258-2997(NDC:27495-014)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 60 mL
MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	10 g in 60 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 60 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BENZOCAINE (UNII: U3RSY48JW5)	
GLYCERYL MONOSTEARATE (UNII: 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: ZY81Z83H0X)	
BORAGE OIL (UNII: F8XAG1755S)	
AMMONIO METHACRYLATE COPOLYMER TYPE A (UNII: 8GQS4E66YY)	
GINGER (UNII: C5529G5JPQ)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68258-2997-9	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/22/2011	

Labeler - Dispensing Solutions, Inc. (066070785)**Registrant** - PSS World Medical, Inc. (101822682)**Establishment**

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(68258-2997) , repack(68258-2997)

