

DENDRACIN NEURODENDRAXCIN- methyl salicylate, menthol and capsaicin lotion

Advanced Rx of Tennessee, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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 persists 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.

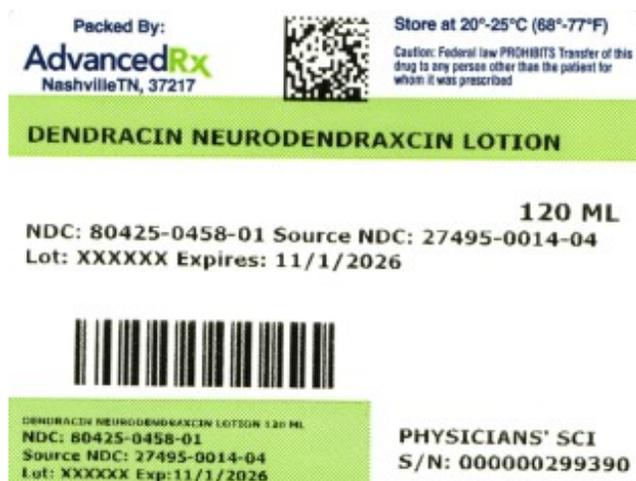
Manufactured for **Physician's Science and Nature Inc.**

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

Distributed by:

Advanced Rx of Tennessee, LLC

Principal Display Panel



DENDRACIN NEURODENDRAXCIN

methyl salicylate, menthol and capsaicin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80425-0458(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	18 g in 60 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 60 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.015 g in 60 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
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 SEED OIL (UNII: F8XAG1755S)	
AMMONIO METHACRYLATE COPOLYMER TYPE A (UNII: 8GQS4E66YY)	
GINGER (UNII: C5529G5JPQ)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (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:80425-0458-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/05/2024	

Labeler - Advanced Rx of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx of Tennessee, LLC		117023142	repack(80425-0458)

Revised: 12/2024

Advanced Rx of Tennessee, LLC