DENDRACIN NEURODENDRAXCIN- methyl salicylate, menthol and capsaicin lotion
Unit Dose Services

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

HOW SUPPLIED

Product: 50436-0165

NDC: 50436-0165-1 120 mL in a BOTTLE

DENDRACIN TOPICAL PAIN RELIEF

DENDRACIN NEURODENDRAXCIN

methyl salicylate, menthol and capsaicin lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-0165(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	300 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 mg in 1 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 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:50436-0165-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2011	

Marketing Information

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

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-0165) , RELABEL(50436-0165)

Revised: 7/2018 Unit Dose Services