

DENDRACIN NEURODENDRAXCIN- methyl salicylate, menthol and capsaicin lotion lotion

DirectRx

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

Methyl Salicylate 30%

Menthol 10%

Capsaicin 0.025%

Topical Analgesic

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.

For temporary relief of mild pain due to muscular strain, arthritis, and simple back pain. Does not cure any disease.

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.

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.

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 Physician's Science and Nature Inc.
220 Newport Center Drive 11-634, Newport Beach, CA 92660

Made in the USA

Patent Pending

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.



DENDRACIN NEURODENDRACIN

methyl salicylate, menthol and capsaicin lotion lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61919-680(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 |
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 0.015 g in 60 mL |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 6 g in 60 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| DIMETHYL SULFOXIDE (UNII: YOW8V9698H) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| AMMONIO METHACRYLATE COPOLYMER TYPE A (UNII: 8GQS4E66YY) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| GINGER (UNII: C5529G5JPQ) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024) | |
| BORAGE SEED OIL (UNII: F8XAG1755S) | |
| POLOXAMER 407 (UNII: TUF21VW3M2) | |
| WATER (UNII: 059QF0KO0R) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| BENZOCAINE (UNII: U3RSY48JW5) | |

| | |
|---|--|
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61919-680-02 | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/14/2021 | |
| 2 | NDC:61919-680-04 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/14/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 09/14/2021 | |

Labeler - DirectRx (079254320)

Registrant - DirectRx (079254320)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|---------------------|
| DirectRx | | 079254320 | relabel(61919-680) |

Revised: 3/2022

DirectRx