DR. DS SUPER 7 PAIN RELIEF- menthyl salicylate and menthol cream Promedx Innovations 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.

Drug Facts

Active Ingredient

Menthyl Salicylate 10% Menthol 2%

Purpose

Topical analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains and sprains
- bruises

Warnings

For external use only

Allergy alert

• do not use if you are allergic to plants of the Asteraceae / Compositae / Daisy family

When using this product

- avoid contact with the eyes and mucous membranes
- do not apply to wounds or damaged skin
- do not bandage tightly
- do not apply with external heat, such as an electric pad, as this may result in excessive skin irritation or skin burn

Ask a healthcare professional before use if you are

• taking anticoagulant medications

Stop using and ask a healthcare professional if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- if a rash develops, or you become hypersensitive and/or burning, blistering or swelling occurs, discontinue use and seek medical help immediately

If pregnant or breast-feeding

• ask a healthcare professional before use

Keep out of reach of children

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

Directions

Adults and children 2 years of age and older:

- shake bottle before use
- apply a thin and even coat to affected area not more than 3 to 4 times daily
- rub and/or massage into skin until the preparation disappears

Children (2 to 12 years old)

- ask a doctor
- application should be supervised by an adult

Other information

- store at room temperature 15°C 30°C (59°F 86°F)
- do not use if quality seal is missing or broken
- store in airtight, light-resistant container

Inactive ingredients

Arnica Montana Flower Extract, Benzoic Acid, Brassica Campestris (Rapeseed) Seed Oil, Citric Acid, Dehydroacetic Acid, Eucalyptus Globulus Leaf Essential Oil, Glycerin, Linum Usitatissimum (Linseed) Seed Extract, MSM, Myristyl Myristate, Neopentyl Glycol Dicaprylate/Dicaprate, Peppermint Oil (Mentha piperita), Phenoxyethanol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Silica, Sodium Stearoyl Glutamate, Water, Xanthan Gum

DR. D'S

SUPER 7

Enhanced Topical Pain Relief

NEW

For relief of:

Muscle, Joint

and Arthritic Pain

TRIPLE CARRIER SYSTEM

- Doctor Developed
- 7 Powerful Natural Ingredients
- Easy to Use Applicator
- Paraben and PEG Free

88 mL

NDC 72246-112-01



DR. DS SUPER 7 PAIN RELIEF

menthyl salicylate and menthol cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72246-112 Route of Administration TOPICAL

| Active Ingredient/Active Moiety | | | |
|---|-------------------|----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 20 mg in 1 mL | |
| MENTHYL SALICYLATE, (+/-)- (UNII: 43XOA705ZD) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 100 mg in 1 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZOIC ACID (UNII: 8 SKN0 B0 MIM) | |
| DEHYDRO ACETIC ACID (UNII: 2KAG279 R6 R) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE (UNII: VLW429K27K) | |
| MYRISTYL MYRISTATE (UNII: 40 42 ZC 00 DY) | |
| BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626) | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | |
| ROSEMARY (UNII: IJ67X351P9) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024) | |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) | |
| WATER (UNII: 059QF0KO0R) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| FLAX SEED (UNII: 4110 YT348 C) | |
| PHENO XYETHANOL (UNII: HIE492ZZ3T) | |

| F | Packaging | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:72246-112- 01 | 1 in 1 CARTON | 09/04/2019 | | | |
| 1 | | 88 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | | | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 09/04/2019 | | |
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Labeler - Promedx Innovations Inc (203749853)

Revised: 1/2021 Promedx Innovations Inc