

## **HEMPVANA PAIN RELIEF- trolamine salicylate cream**

**Neutraderm, 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.*

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### **Hempvana Pain Relief Cream**

#### ***Drug Facts***

##### ***Active Ingredient:***

Trolamine Salicylate (10%)

##### ***Purpose***

Topical Analgesic

##### ***Uses***

Temporarily relieves minor pain associated with:

- arthritis • simple backache • muscle strains • sprains • bruises

##### ***Warnings***

##### **For external use only**

**Allergy alert:** If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

##### **When using this product**

- Use only as directed. Read and follow all directions and warnings on this label.
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use.
- Avoid contact with eyes or mucous membranes.
- Do not apply to wounds or damaged, broken or irritated skin
- Do not use at the same time as other topical analgesics.

##### **Stop use and ask a doctor if**

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Redness is present or irritation develops

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children and pets.** If swallowed, get medical help or contact a Poison Control Center right away.

##### ***Directions***

- ***For Use By Adults Only***
- Apply generously to affected area.
- Massage into painful area until thoroughly absorbed into skin.
- Repeat as necessary, but no more than 4 times daily.

## Inactive Ingredients

Water/Aqua, Ethylhexyl Stearate, Butylene Glycol, Dimethicone, Stearic Acid, Caprylic/Capric Triglyceride, Cannabis Sativa Seed Oil (Hemp Seed Oil), Glyceryl Stearate, PEG-100 Stearate, Cetostearyl Alcohol, Sunflower Oil, Allantoin, Tocopheryl Acetate, Ethylhexylglycerin, Isohexadecane, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Caprylyl Glycol, Hexylene Glycol, Polysorbate 80, Disodium EDTA, D&C Green No. 5 (CI 61570), Sodium Hydroxide, Phenoxyethanol

## Questions?

Call (855) 877-4503 (M-F, 9am-5pm EST)

## MAXIMUM STRENGTH

Enriched With *Hemp Seed*\* Extract

## ODOR FREE!

Phthalate Free Paraben Free Vegan Gluten Free Cruelty Free

• No Irritation • No Burning • Non Greasy

**Hempvana® Pain Relief Cream** absorbs quickly and goes to work instantly. Its unique formula includes a proven active ingredient plus the moisturizing benefit of cold pressed hemp seed\* extract for soothing relief to back, neck, shoulders, feet, wrists, calves and more.

TAMPER EVIDENT: Do not use if safety seal on cap is broken or missing.

For more information, visit [www.HempvanaStore.com](http://www.HempvanaStore.com)

**\*Complies with Federal Law. Hemp seed extract contains no detectible tetrahydrocannabinol (THC) or cannabidiol (CBD), Derived from the cannabis industrial hemp cultivar.**

Dist. by: Telebrands Corp.

79 Two Bridges Road,

Fairfield, NJ 07004

**Hemp • Health • Happiness™**

## Packaging

### Label-1





## Label-2



## Drug Facts

| Drug Facts  |                   |
|---|-------------------|
| <b>Active Ingredient</b>  | <b>Purpose</b>    |
| Trolamine Salicylate 10%  | Topical Analgesic |
| <b>Uses</b> temporarily relieves minor pain associated with:  |                   |
| • arthritis • simple backache • muscle strains • sprains • bruises  |                   |
| <b>Warnings</b>   |                   |
| <b>For external use only</b>  |                   |
| <b>Allergy alert:</b> If prone to allergic reaction from aspirin or salicylates, consult a doctor before use. |                   |
| <b>When using this product</b>  |                   |
| • Use only as directed. Read and follow all directions and warnings on this label.                            |                   |

| Drug Facts (continued)   |  |
|--|--|
| If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.   |  |
| <b>Directions</b>  |  |
| • For Use By Adults Only   |  |
| • Apply generously to affected area  |  |
| • Massage into painful area until thoroughly absorbed into skin.   |  |
| • Repeat as necessary, but no more than 4 times daily.   |  |
| <b>Inactive Ingredients</b> Water/Aqua, Ethylhexyl Stearate, Butylene Glycol, Dimethicone, Stearic Acid, Caprylic/Capric Triglyceride, Cannabis Sativa Seed Oil, Glyceryl Stearate, PEG-100 Stearate, Cetostearyl Alcohol, Sunflower Oil, Allantoin, Tocopheryl Acetate, Ethylhexylglycerin, Isohexadecane, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Caprylyl Glycol, Hexylene Glycol, Polysorbate 80, Diodium EDTA, D&C Green No. 5 (CI 61570), Sodium Hydroxide, Phenylethanol |  |

- Do not bandage tightly or apply local heat (such as heating pads) to the area of use.
  - Avoid contact with eyes or mucous membranes.
  - Do not apply to wounds or damaged, broken or irritated skin.
  - Do not use at the same time as other topical analgesics.
- Stop use and ask a doctor if
- Condition worsens
  - Symptoms persist for more than 7 days or clear up and occur again within a few days
  - Redness is present or irritation develops

Acetate, Ethylhexylglycerin, Isohexadecane, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Caprylyl Glycol, Hexylene Glycol, Polysorbate 80, Disodium EDTA, D&C Green No. 5 (CI 61570), Sodium Hydroxide, Phenoxyethanol

Questions? Call (855) 877-4503 (M-F, 9am-5pm EST)

## HEMPVANA PAIN RELIEF

trolamine salicylate cream

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:39765-011 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength    | Strength      |
|--|----------------------|---------------|
| TROLAMINE SALICYLATE (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ) | TROLAMINE SALICYLATE | 10 g in 100 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R)   |          |
| ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)   |          |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)   |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)   |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)  |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)  |          |
| CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)  |          |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)   |          |
| PEG-100 STEARATE (UNII: YD01N1999R)  |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)   |          |
| SUNFLOWER OIL (UNII: 3W1JG795YI)   |          |
| ALLANTOIN (UNII: 344S277G0Z)   |          |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)                                       |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)  |          |
| ISOHEXADECANE (UNII: 918X1OUF1E)   |          |
| SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX) |          |
| CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)         |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)   |          |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J)   |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)  |          |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)  |          |
| D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)   |          |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)  |          |

| Product Characteristics |  |   |                      |                    |
|-------------------------|--|---|----------------------|--------------------|
| Color                   | green (Pale Green to Light Green)        |   | Score                |                    |
| Shape                   |  |   | Size                 |                    |
| Flavor                  |  |   | Imprint Code         |                    |
| Contains                |  |   |                      |                    |
|                         |  |   |                      |                    |
| Packaging               |  |   |                      |                    |
| #                       | Item Code                                | Package Description                               | Marketing Start Date | Marketing End Date |
| 1                       | NDC:39765-011-01                         | 1 in 1 CARTON                                     | 01/10/2019           |                    |
| 1                       |  | 119 g in 1 JAR; 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                                  |   | 01/10/2019           |                    |

**Labeler** - Neutraderm, Inc. (146224444)

| Establishment    |         |           |                        |
|------------------|---------|-----------|------------------------|
| Name             | Address | ID/FEI    | Business Operations    |
| Neutraderm, Inc. |         | 146224444 | manufacture(39765-011) |