

**HOLUS RELIEF CREAM- menthol, camphor cream**  
**Nemadji Management, LLC**

*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.*

-----

**DESCRIPTION**

Holus Relief Cream, 1.7 oz - menthol, camphor cream

Holus Relief Cream, 4 oz - menthol, camphor cream

Topical analgesic, Over-The-Counter drug

1.7 ounces of topical analgesic cream in a pump dispenser

4 ounces of topical analgesic cream in a container

*Disclaimer: Most OTC drugs are not reviewed and approved by the FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

**ACTIVE INGREDIENTS**

MENTHOL 3.9%

CAMPHOR 0.4%

**PURPOSE**

FOR THE TEMPORARY RELIEF OF MINOR ACHES AND PAINS OF MUSCLES AND JOINTS ASSOCIATED WITH SIMPLE BACKACHE, ARTHRITIS, STRAINS, BRUISES AND SPRAINS.

**DIRECTIONS**

APPLY TO INFLAMED & SORE AREA NO MORE THAN 3-4 TIMES PER DAY. ADULTS AND CHILDREN 2 YEARS OF AGE AND OLDER; CHILDREN UNDER 2 YEARS OF AGE: CONSULT A PHYSICIAN.

**DOSAGE & ADMINISTRATION**

APPLY TO INFLAMED & SORE AREA NO MORE THAN 3-4 TIMES PER DAY.

**WARNINGS**

FOR EXTERNAL USE ONLY

AVOID CONTACT WITH EYES

DO NOT APPLY: TO WOUNDS OR DAMAGED SKIN

ALLERGY: PRODUCT CONTAINS COCONUT

THE SAFETY OF THIS PRODUCT HAS NOT BEEN DETERMINED.

THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE

**WARNINGS, Holus Relief Cream**

STOP AND ASK A PHYSICIAN (IF CONDITION WORSENS, SYMPTOMS PERSIST MORE THAN 7 DAYS, CONDITION RECURS AFTER A FEW DAYS).

**WARNING - PREGNANCY OR BREAST FEEDING**

IF PREGNANT OR BREASTFEEDING, SEE PHYSICIAN BEFORE USE

**INACTIVE INGREDIENTS**


PURIFIED WATER, SHEA BUTTER, UNREFINED COCONUT OIL, STEARIC ACID, WILLOW BARK EXTRACT, CETYL PALMITATE,

JOJOBA OIL, COCOA BUTTER, ARNICA EXTRACT, SUNFLOWER OIL, GLYCERYL STEARATE, VITAMIN E ACETATE, GRAPSEED OIL, AVOCADO OIL, MSM (METHYLSULFONYLMETHANE), RICE BRAN OIL, XANTHAN GUM, SORBIC ACID, GLYCERIN, TETRASODIUM GLUTAMATE DIACETATE, SODIUM BENZOATE, SODIUM HYDROXIDE, CITRIC ACID, PEPPERMINT OIL, HEMP EXTRACT, BOSWELLIA SERRATA EXTRACT.


**PRICIPAL DISPLAY PANEL**

VEGAN • NON-GMO • GMP  
PARABEN FREE • CLEAN  
LABEL • MADE IN USA

**REORDER**



holusnaturals.com  
715-318-0026



hōlus • 500 Stimson Dr.  
Osceola, WI 54002  
sales@holusnaturals.com

hōlus

**relief**  
cream

1.7 fl oz

**Drug Facts**

**Active Ingredients**

Menthol 3.9% ..... Topical analgesic  
Camphor 0.4% ..... Topical analgesic

**Purpose**

**Uses** ■ temporary relief of minor aches & pains associated with: ■ simple backache  
■ arthritis ■ sprains, strains and bruises

**Warning** ■ for external use only ■ avoid contact with eyes ■ do not apply: to wounds or damaged skin ■ stop use and ask a physician if condition worsens, symptoms persist more than 7 days, condition reoccurs after a few days ■ keep out of reach of children ■ if pregnant or breastfeeding, see physician before use ■ allergy alert: product contains coconut ■ the safety of this product has not been determined ■ this product is not intended to diagnose, treat, cure, or prevent any disease

**Directions for use** ■ Apply to inflamed & sore area no more than 3-4 times per day. ■ adults and children 2 years of age and older; children under 2 years of age: consult a physician

**Other information** Store in cool, dry place, away from direct sun.

**Inactive ingredients** Purified Water, Stearic Acid, Coconut Oil, Willow Bark Extract, Shea Butter, Cetyl Palmitate, Jojoba Oil, Coco Butter, Arnica Extract, Sunflower Oil, Glyceryl Stearate, Vitamin E Acetate, Grapeseed Oil, Avocado Oil, MSM (Methylsulfonylmethane), Rice Bran Oil, Xanthan Gum, Sorbic Acid, Glycerin, Tetrasodium Glutamate Diacetate, Sodium Benzoate, Sodium Hydroxide, Citric Acid. For aroma: Peppermint Oil, Hemp Extract (aerial parts, 167mg), Boswellia serrata Extract

**Questions** 715-318-0026; Monday-Friday, 9:00am-4:30pm (CT)

VEGAN • NON-GMO • GMP  
PARABEN FREE • CLEAN  
LABEL • MADE IN USA

**REORDER**



holusnaturals.com  
715-318-0026

VEGAN • NON-GMO  
PARABEN FREE  
CLEAN LABEL • GMP  
MADE IN USA

hōlus • 500 Stimson Dr.  
Osceola, WI 54002  
sales@holusnaturals.com

hōlus

**relief**  
cream

4 fl oz

**Drug Facts**

**Active Ingredients**

Menthol 3.9% ..... Topical analgesic  
Camphor 0.4% ..... Topical analgesic

**Purpose**

**Uses** ■ temporary relief of minor aches & pains associated with: ■ simple backache  
■ arthritis ■ sprains, strains and bruises

**Warning** ■ for external use only ■ avoid contact with eyes ■ do not apply: to wounds or damaged skin ■ stop use and ask a physician if condition worsens, symptoms persist more than 7 days, condition reoccurs after a few days ■ keep out of reach of children ■ if pregnant or breastfeeding, see physician before use ■ allergy alert: product contains coconut ■ the safety of this product has not been determined ■ this product is not intended to diagnose, treat, cure, or prevent any disease

**Directions for use** ■ Apply to inflamed & sore area no more than 3-4 times per day. ■ adults and children 2 years of age and older; children under 2 years of age: consult a physician

**Other information** Store in cool, dry place, away from direct sun.

**Inactive ingredients** Purified Water, Stearic Acid, Coconut Oil, Willow Bark Extract, Shea Butter, Cetyl Palmitate, Jojoba Oil, Coco Butter, Arnica Extract, Sunflower Oil, Glyceryl Stearate, Vitamin E Acetate, Grapeseed Oil, Avocado Oil, MSM (Methylsulfonylmethane), Rice Bran Oil, Xanthan Gum, Sorbic Acid, Glycerin, Tetrasodium Glutamate Diacetate, Sodium Benzoate, Sodium Hydroxide, Citric Acid. For aroma: Peppermint Oil, Hemp Extract (aerial parts, 400mg), Boswellia serrata Extract

**Questions** 715-318-0026; Monday-Friday, 9:00am-4:30pm (CT)

# HOLUS RELIEF CREAM

menthol, camphor cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73278-210
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	3.9 g in 100 g
<b>CAMPHOR OIL</b> (UNII: 75IZZ8Y727) (CAMPHOR OIL - UNII:75IZZ8Y727)	CAMPHOR OIL	0.4 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WILLOW BARK</b> (UNII: S883J9JDYX)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>RICE BRAN OIL</b> (UNII: LZ06K1506A)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>CANNABIDIOL</b> (UNII: 19GBJ60SN5)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>BOSWELLIA SERRATA RESIN OIL</b> (UNII: 5T1XCE6K8K)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

## Product Characteristics

<b>Color</b>	white (White to slightly off-white, opaque)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:73278-210-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/24/2023	
2	NDC:73278-210-04	118 g in 1 CONTAINER; Type 0: Not a Combination Product	04/24/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/24/2023	

**Labeler** - Nemadji Management, LLC (100279564)

**Registrant** - Nemadji Management, LLC (100279564)

## Establishment

Name	Address	ID/FEI	Business Operations
Nemadji Management, LLC		100279564	manufacture(73278-210)