HOLUS RELIEF GEL, 1.7 OZ- menthol, camphor gel 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.

HOLUS RELIEF GEL, 1.7 OZ

DESCRIPTION

Holus Relief Gel, 1.7oz - menthol, camphor gel

Topical analgesic, Over-The-Counter drug

1.7oz ounces of topical analgesic gel in a pump dispenser

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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, Holus Relief Gel, 1.7oz

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 SECTION

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

KEEP OUT OF REACH OF CHILDREN

WARNINGS, Holus Relief Gel, 1.7oz

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

IF PREGNANT OR BREASTFEEDING, SEE PHYSICIAN BEFORE USE

INACTIVE INGREDIENTS, Holus Relief Gel (1.7oz)

PURIFIED WATER, ISOPROPYL ALCOHOL, WITCH HAZEL, ALOE VERA GEL, COCONUT OIL, JOJOBA OIL, GLYCERIN, ARNICA EXTRACT, BOSWELLIA SERRATA EXTRACT, MSM (METHYLSULFONYLMETHANE), CARBOMER, VITAMIN E ACETATE, TETRASODIUM GLUTAMATE DIACETATE, SODIUM BENZOATE, SODIUM HYDROXIDE, CITRIC ACID, PEPPERMINT OIL, EUCALYPTUS OIL, WILLOW BARK EXTRACT, HEMP EXTRACT (AERIAL PARTS, 222MG)

PRINCIPAL DISPLAY



Active ingredients Menthol 3.9% Camphor 0.4%	Purpose Topical analgesic Topical analgesic
Uses ■temporary relief of minor aches & pains associated with: ■arthritis ■sprains, strains and bruises	■simple backache
Warning for external use only Bavold contact with eyes Idea damaged skin Batop use and sek a physician if condition worsens, symp 7 days, condition reoccurs after a few days Ikee set of reach of childs breastfeeding, see physician before use Bailergy alert: product can safety of this product has not been determined Bailergy alert: product is not inte cure, or prayent any disease Directions for use Bapply to inflamed & sore area no more than 3-4 Badults and children 2 years of age and older; children under 2 years of age	toms persist more than ten — of pregnant of tains coconut — other anded to diagnose, treat

Unactive ingredients Purified Water, Isopropyl Alcohol, Witch Hazel, Aloe Vera Gel, Coconut Oll, Jojoba Oll, Glycerin, Arnica Extract, Boswellia serrata Extract, MSM (Methylsulfonylmethane), Carbomer, Vitamin E Acetate, Tetrasodiutm Glutamate Diacetate, Sodium Benzoate, Sodium Hydroxide, Citric Aold. For aroma: Peppermint Oll, Eucalyptus Oll, Willow Bark Extract, Hemp Extract (aerial parts, 222mg)

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



HOLUS RELIEF GEL, 1.7 OZ

menthol, camphor gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73278-202
Route of Administration	TOPICAL		

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

Inactive Ingredients

Ingredient Name	Strength
CANNABIDIOL (UNII: 19GBJ60SN5)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
JOJOBA OIL (UNII: 724GKU717M)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WITCH HAZEL (UNII: 101I4J0U34)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WILLOW BARK (UNII: S883J9JDYX)	
GLYCERIN (UNII: PDC6A3C0OX)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
EUCALYPTUS OIL (UNII: 2R040NI662)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	

Product Characteristics			
Color	white (transparent gel)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73278- 202-50	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2023	
2	NDC:73278- 202-03			

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(73278-202)

Revised: 4/2023 Nemadji Management, LLC