

**NECK AND LUMBAR PAIN RELIEVING BALM- camphor, menthol, and methyl salicylate oil
MADISON ONE ACME 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

Camphor 11%

Menthol 16%

Methyl salicylate 30%

Purpose

External analgesic

External analgesic

External analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

- on irritated or damaged skin
- on wounds

Ask a doctor or pharmacist before use if you have

- any concerns about using this product

When using this product

- do not use otherwise than as directed
- ☐■ avoid contact with the eyes or mucous membranes☐
- do not bandage tightly☐
- do not apply heat to the area in the form of heating pads, hot water bottles, or lamps (doing so increases the risk of serious burns)

Stop use and ask a doctor if

- condition worsens☐
- symptoms persist for more than 7 days
- ☐■ symptoms clear up and occur again within a few days☐

- excessive irritation of the skin develops
- nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs
- you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation)
- when using for pain of arthritis:
 - pain persists for more than 10 days
 - redness is present
 - in conditions affecting children under 12 years of age

Report any unexpected side effects from the use of this product to the FDA MedWatch Program

Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 3 years of age and older: apply several drops and rub into the affected area not more than 3 to 4 times daily
- children under 3 years of age: consult your physician

Other information

- keep container tightly closed
- store protected from light at 15 °to 30 C (59 to 86 F)

Inactive ingredients

angelica sinensis root, biancaea sappan wood, citrus aurantium fruit, crassostrea gigas shell, cyathula officinalis root, dipsacus asper root, dragon's blood, eucommia ulmoides bark, frankincense, leonurus japonicus flowering top, ligusticum sinense subsp. chuanxiong root, myrrh, olive oil, panax notoginseng root, rubia cordifolia root, safflower, salvia miltiorrhiza root, senegalia catechu wood, spatholobus suberectus stem, taxillus chinensis top and white wax.

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

- you may also report serious side effects to this phone number

NECK & LUMBAR PAIN RELIEVING BALM

NDC 55614-660-01

EXTERNAL ANALGESIC

CAMPHOR, MENTHOL, METHYL SALICYLATE

2.82 OZ (80 G)



NECK AND LUMBAR PAIN RELIEVING BALM			
camphor, menthol, and methyl salicylate oil			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:556 14-660
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)		CAMPHOR (SYNTHETIC)	11 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	16 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)		METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
BIANCAEA SAPPAN WOOD (UNII: 086263LQDD)	
CITRUS AURANTIUM FRUIT (UNII: DQD16J2B5O)	
CRASSOSTREA GIGAS SHELL (UNII: 5I0R0U8ZL0)	
CYATHULA OFFICINALIS ROOT (UNII: BRM37UP34O)	
DIPSACUS ASPER ROOT (UNII: LB1GQP4253)	
DRAGON'S BLOOD (UNII: M3YJ2C28IC)	
EUCOMMIA ULMOIDES BARK (UNII: L878N1L0AR)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
LEONURUS JAPONICUS FLOWERING TOP (UNII: V315CCZ08Z)	
LIGUSTICUM SINENSE SUBSP. CHUANXIONG ROOT (UNII: RR83T99U97)	
MYRRH (UNII: JC71GJ1F3L)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PANAX NOTOGINSENG ROOT (UNII: GQX1C1175U)	
RUBIA CORDIFOLIA ROOT (UNII: 4V873H15CG)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
SALVIA MILTIORRHIZA ROOT (UNII: 1693AM5SBN)	
SENEGALIA CATECHU WOOD (UNII: CHL342Y4LA)	
SPATHOLOBUS SUBERECTUS STEM (UNII: N51VZ363BA)	
TAXILLUS CHINENSIS TOP (UNII: QJ523LD71P)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-660-01	1 in 1 BOX	05/15/2020	
1		80 g in 1 BOTTLE, GLASS; 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	05/15/2020	

Labeler - MADISON ONE ACME INC (096196758)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-660)