

**YULAM DIE DA WAN HUA PAIN RELIEVING- menthol and camphor 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

Menthol 3%

Camphor 4%

Purpose

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 wounds
- on irritated or damaged skin

When using this product

- avoid contact with the eyes or mucous membranes
- do not bandage tightly

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
- 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 2 years of age and older: Apply to affected area and rub gently. Do not use for more than 4 times a day.
- children under 2 years of age: Do not use, consult a doctor.

Other information

- keep container tightly closed
- store in a cool dry place away from sunlight

Inactive ingredients angelica dahurica (bai zhi) root, angelica pubescens (du huo) root, camellia oil, carthamus tinctorius (hong hua) flower bud, chimonanthus praecox (la mei hua) flower, chrysanthemum indicum (yeh chu hua) flower, curcuma involucrata (tu tian qi) root, cynanchum paniculatum (xu chang pu) root, drynaria fortunei (gu sui bu) root, gardenia jasminoides (zhi zi) fruit, ginger (jiang) root, gleditsia sinensis (da zao jiao) fruit, pueraria montana var. lobata (ge hua) flower top, ligusticum sinense (chuan xiong) root, lindera aggregata (wu yao) root, mentha canadensis (bo he) oil, notopterygium incisum (qiang huo) root, paeonia x suffruticosa (mu dan pi) root bark, rheum palmatum (da huang) root, saphoshnikovia divaricata (fang feng) root, shellac, syzygium nervosum flower bud, tangerine (qing pi) unripe peel, tangerine (chen pi) peel, xanthium strumarium (cang er zi) fruit, zanthoxylum nitidum (liang mian zhen) root.

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

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

YULAM DIE DA WAN HUA PAIN RELIEVING OIL

NDC 55614-740-01

EXTERNAL ANALGESIC

1.7 FL OZ (50 ML)

Yulam Wan Hua Oil Unit Box
 Size: 139mm x 38mm x 38mm
 10/31//2022



YULAM DIE DA WAN HUA PAIN RELIEVING

menthol and camphor oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-740
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
ANGELICA PUBESCENS ROOT (UNII: 0MF1EI01KJ)	
CAMELLIA OIL (UNII: T1PE06G0VE)	
CARTHAMUS TINCTORIUS FLOWER BUD (UNII: B86IS27400)	
CHIMONANTHUS PRAECOX WHOLE (UNII: 5Y143KS0YL)	
CHRYSANTHEMUM INDICUM FLOWER (UNII: I6OER6U04L)	
CURCUMA INVOLUCRATA ROOT (UNII: EW5ECF6XAX)	
CYNANCHUM PANICULATUM ROOT (UNII: CZP7EPR012)	
DRYNARIA FORTUNEI ROOT (UNII: 731W842X8Q)	
GARDENIA JASMINOIDES FRUIT (UNII: 7CTH8MD549)	
GINGER (UNII: C5529G5JPQ)	
GLEDITSIA SINENSIS FRUIT (UNII: A6W0J6U07Q)	
PUERARIA MONTANA VAR. LOBATA FLOWERING TOP (UNII: HAM6R1WA7O)	
LIGUSTICUM SINENSE ROOT (UNII: 32SLT970XO)	
LINDERA AGGREGATA ROOT (UNII: 517Q7XRT2T)	
MENTHA CANADENSIS WHOLE (UNII: J1BO4MHT2L)	
NOTOPTERYGIUM INCISUM ROOT (UNII: 5Z2VW4J6RI)	
PAEONIA X SUFFRUTICOSA ROOT BARK (UNII: BUG255FE7X)	
RHEUM PALMATUM ROOT (UNII: G025DAL7CE)	
SAPOSHNIKOVIA DIVARICATA ROOT (UNII: 8H84LFK2QD)	
SHELLAC (UNII: 46N107B71O)	
SYZYGIUM NERVOSUM FLOWER BUD (UNII: 7FA55IY5H8)	
TANGERINE PEEL, UNRIPE (UNII: B077C3NLJV)	
TANGERINE PEEL (UNII: JU3D414057)	
XANTHIUM STRUMARIUM FRUIT (UNII: TN770YC17C)	
ZANTHOXYLUM NITIDUM ROOT (UNII: L2CQZ81759)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-740-01	1 in 1 BOX	11/02/2022	
1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
OTC monograph not final	part348	11/02/2022	

Labeler - MADISON ONE ACME INC (096196758)

Establishment

Name	Address	ID/FEI	Business Operations
GUANGZHOU BAIYUNSHAN JINGXIUTANG PHARMACEUTICAL CO., LTD.		654032218	manufacture(55614-740)

Revised: 11/2022

MADISON ONE ACME INC