

WHITE FLOWER STRAIN RELIEF - camphor, menthol and methyl salicylate oil
JELMA PHILIPPINES 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 ingredients

Camphor 10%

Menthol 15%

Methyl Salicylate 50%

Purpose

External Analgesic

Uses

Temporarily relieves 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
- otherwise than as directed

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 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

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 on the affected area not more than 3 to 4 times daily.

After applying the product, a warm pad may be placed on the affected area for 10 minutes and then massage gently.

- children under 3 years of age: do not use, consult your physician
- refer to the above warnings; use otherwise than as directed may be dangerous

Other information

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

WHITE FLOWER STRAIN RELIEF

camphor, menthol and methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51681-0041
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	10 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	15 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	50 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BETA CAROTENE (UNII: 01YAE03M7J)	
CHINESE CINNAMON OIL (UNII: A4WO0626T5)	
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	
D&C RED NO. 17 (UNII: ND733RX3JN)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51681-0041-1	50 mL in 1 BOTTLE, GLASS		
2	NDC:51681-0041-2	25 mL in 1 BOTTLE, GLASS		
3	NDC:51681-0041-3	3 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/20/2012	

Labeler - JELMA PHILIPPINES INC (721085447)

Establishment

Name	Address	ID/FEI	Business Operations
JELMA PHILIPPINES INC		721085447	repack

Establishment

Name	Address	ID/FEI	Business Operations
HOE HIN PAK FAH YEOW MANUFACTORY LTD		686359001	manufacture

Revised: 2/2012

JELMA PHILIPPINES INC