

WHITE FLOWER ANALGESIC BALM FLORAL SCENTED - 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 5.4%

Menthol 13.1%

Methyl salicylate 36%

Purpose

External analgesic

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

- simple backache
- arthritis
- strains
- bruises
- sprains

Do not use

- on irritated or damaged skin
- on wounds
- 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 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

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 one to two drops to the affected area not more than 3 to 4 times daily. Massage gently.

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

Other information

- keep tightly sealed
- store at or below 30° C (86° F), away from direct sunlight

Inactive ingredients eucalyptus oil, fragrance, lavender oil, and peppermint oil.

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

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

WHITE FLOWER ANALGESIC BALM FLORAL SCENTED NDC-51681-0011-1 0.338 FL OZ (10 ML)



和興白花油 (清幽) 07.2010
 White Flower Analgesic Balm Floral Scented
 Unit box 紙盒平面設計檔案



WHITE FLOWER ANALGESIC BALM FLORAL SCENTED

camphor, menthol and methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51681-0011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5.4 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	13.0 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	35.8 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51681-0011-1	10 mL in 1 BOTTLE, GLASS		
2	NDC:51681-0011-2	5 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	07/20/2010	

Labeler - JELMA PHILIPPINES INC (721085447)

Revised: 7/2010

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