

**WHITE FLOWER ANALGESIC BALM- 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.*

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**DRUG FACTS**

**Active ingredients**

Camphor 6%

Menthol 15%

Methyl salicylate 40%

**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 wounds
- on irritated or damaged skin
- on the face
- otherwise than as directed

**Warnings**

For external use only

**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 a few drops then gently rub into the affected area not more than 3 to 4 times daily.
- Children under 3 years of age: Do not use, consult your doctor.
- Refer to the above warnings; use otherwise than as directed may be dangerous.

**Other information**

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

**Inactive ingredients**

Eucalyptus oil, lavender oil and peppermint oil.

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

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

WHITE FLOWER ANALGESIC BALM NDC-51681-0001-1 0.67 fl oz (20mL)



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 camphor, menthol, and methyl salicylate oil

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51681-0001
<b>Route of Administration</b>	TRANSDERMAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	6 g in 100 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14.6 g in 100 mL
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	40 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51681-0001-1	20 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/14/2010	
2	NDC:51681-0001-2	10 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/14/2010	
3	NDC:51681-0001-4	2.5 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/14/2010	
4	NDC:51681-0001-3	5 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	06/14/2010	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC mono graph not final	part348	06/14/2010	

**Labeler** - JELMA PHILIPPINES INC (721085447)