

**BALSAMO DE UBRE MASCURA- methyl salicylate ointment  
Menper Distributors 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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**Active Ingredient**

Methyl Salicylate 10.5 % .....Topical Analgesic

**Uses**

Topical Analgesic

**Uses**

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains and sprains

**Warnings**

For external use only.

Avoid contact with the eyes.

Do not use otherwise than as directed

**Do not use with a heating pad**

- with a bandage
- on wounds or damaged skin
- over extensive areas of the body
- with a heating pad
- on a child under 12 years of age
- on irritated skin

**Stop use and ask a doctor immediately if**

- pain persists for more than 7 days, redness is present, or in conditions affecting children under 12 years of age
- excessive irritation of skin develops
- condition worsens

**If pregnant or breast-feeding,**

ask a health professional before use.

## Keep out of reach of children to avoid accidental poisoning.

If swallowed, induce vomiting and call a physician or contact a Poison Control Center right away.

### Directions

- Adults and Children 12 years and older: apply generously and gently massage into painful area until the product disappears. Apply into affected area not more than 3 to 4 times daily
- Children under 12 years of age: ask a doctor

### Other Information

Store at 15° C to 25° C (59° F to 77° F)

### Inactive ingrediets

camphor, D&C yellow #10, menthol, methylparaben, paraffin wax, propylparaben, white petrolatum.

### Questions?

call 1-800-560-5223 M-F 9 AM to 4 PM Eastern



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## BALSAMO DE UBRE MASCURA

methyl salicylate ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53145-401
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10.5 g in 90 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-401-03	90 g in 1 CONTAINER; Type 0: Not a Combination Product	05/10/2011	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/10/2011	

**Labeler** - Menper Distributors Inc. (101947166)

Revised: 2/2022

Menper Distributors Inc.