BEE BRAND MEDICATED- menthol and camphor oil PT. TAWON JAYA MAKASSAR

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

Menthol 2.2% 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
- if excessive irritation develops
- over extensive parts of the body
- if you are allergic to any ingredients in this product

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 clear up and occur again within a few days
- symptoms persist for more than 7 days

- nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs
- when using for pain of arthritis if:
 - in conditions affecting children under 12 years of age
 - redness is present
 - pain persists for more than 10 days

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 with cotton not more than 3 to 4 times daily.
- Children under 2 years of age: Do not use, consult a doctor.

Other information

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

Inactive ingredients

Achyranthes root, boesenbergia rotunda root, burpleurum falcatum root, cajuput oil, ceylon citronella root, cinnamomum culilawan leaf oil, coconut oil, garlic bulb, ginger root, greater galangal root, hance pepper aerial parts, onion bulb, pepper root, pubescent angelica root, Saigon cinnamon, turmeric root, turpentine oil, and West Indian lemongrass oil.

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

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

BEE BRAND MEDICATED OIL
NDC 66525-056-01
EXTERNAL ANALGESIC
3 FL OZ (90 mL)



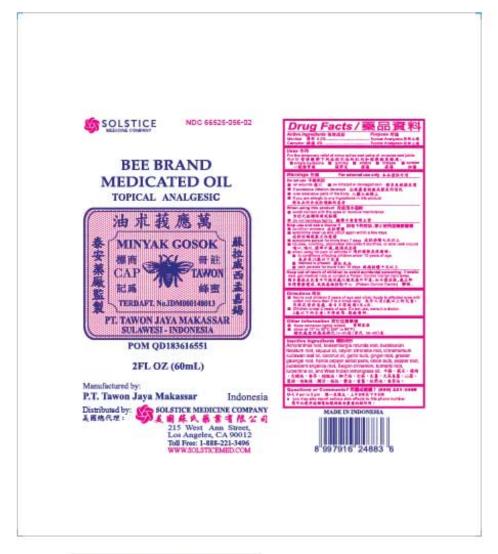


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NDC 66525-056-02 EXTERNAL ANALGESIC 2 FL OZ (60 mL)







BEE BRAND MEDICATED

menthol and camphor oil

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66525-056

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.2 mg in 100 mL	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4 mg in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
ACHYRANTHES BIDENTATA ROOT (UNII: 5QIU26R6P1)	
BOESENBERGIA ROTUNDA ROOT (UNII: J7TKP1SS3G)	
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)	
CAJUPUT OIL (UNII: J3TO6BUQ37)	
CYMBOPOGON NARDUS WHOLE (UNII: A9TR1GFH5L)	
CINNAMOMUM CULILABAN LEAF OIL (UNII: HAG3U9ZKA6)	
COCONUT OIL (UNII: Q9L0073W7L)	
GARLIC (UNII: V1V998DC17)	
GINGER (UNII: C5529G5JPQ)	
GREATER GALANGAL (UNII: 7Y64R856MB)	
PIPER HANCEI TOP (UNII: AMU868N7QW)	
ONION (UNII: 492225Q21H)	
PIPER NIGRUM WHOLE (UNII: 49L10LI8DN)	
ANGELICA PUBESCENS ROOT (UNII: 0MF1EI01KJ)	
CINNAMOMUM LOUREIROI WHOLE (UNII: 7N878U293P)	
TURMERIC (UNII: 856YO1Z64F)	
TURPENTINE OIL (UNII: C5H0QJ6V7F)	
CITRONELLA OIL (UNII: QYO8Q067D0)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66525- 056-01	1 in 1 BOX	06/03/2021		
1		90 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product			
2	NDC:66525- 056-02	1 in 1 BOX	06/30/2021		
2		60 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	06/03/2021			

Labeler - PT. TAWON JAYA MAKASSAR (726639268)

Establishment					
Name	Address	ID/FEI	Business Operations		
PT. TAWON JAYA MAKASSAR		726639268	manufacture(66525-056)		

Revised: 6/2021 PT. TAWON JAYA MAKASSAR