

HERBAL BALM- methyl salicylate, menthol and cream

Big 5 Nutrition LLC

Herbal Balm

Drug Facts

Active Ingredients

Methyl Salicylate 20.7%

Menthol 15.6%

Camphor 3.1%

Purpose

External analgesic

Uses

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

- arthritis
- strains
- bruises
- sprains
- simple backache

Warnings

For external use only

Do not use

- on wounds
- irritated or damaged skin
- sensitive skin
- with a heating pad
- if pregnant
- with, or as the same time as, other external analgesic products
- if allergic to aspirin or salicylates
- if allergic to any ingredients of this product

When using this product

- avoid contact with eyes
- do not bandage tightly
- do not apply to wounds or damaged skin
- do not use 1 hour before or after bathing

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
- redness is present
- side effects occur

If pregnant, ask a health professional before use.

Keep out of reach of children to avoid accidental poisoning

In case of overdose, get medical help or contact a Poison Control Center right away.

Do not use otherwise than as directed.

Directions

- Apply to the affected area. Rub well on affected area.
- Repeat 2 times daily.
- Children under 2 years of age: Do not use or consult a doctor.

Other Information

- Store at room temperature, 20 to 25°C (68 to 77°F)

Other Ingredients

Eucalyptus Oil, Lavender Oil, Vaseline, White beeswax.

Questions or Comments?

Tel: 714-531-2020

Web: tnduocthao.com

Principal Display Panel

<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none">■ 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■ redness is present ■ side effects occur. <p>If pregnant, ask a health professional before use. Keep out of reach of children to avoid accidental poisoning. In case of overdose, get medical help or contact a Poison Control Center right away. Do not use otherwise than as directed.</p> <p>Directions</p> <ul style="list-style-type: none">■ Apply to the affected area. Rub well on affected area.■ Repeat 2 times daily.■ Children under 2 years of age: Do not use or consult a doctor. <p>Other Information</p> <ul style="list-style-type: none">■ Store at room temperature, 20 to 25°C(68 to 77°F) <p>Inactive Ingredients Eucalyptus oil, Lavender oil, Vaseline, White beeswax.</p> <p>Question or Comments? Tel: 714-531-2020 Web: tnduocthao.com</p>		<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Methyl Salicylate 20.7%.....</td><td>External Analgesic</td></tr><tr><td>Menthol 15.6%.....</td><td>External Analgesic</td></tr><tr><td>Camphor 3.1%.....</td><td>External Analgesic</td></tr></tbody></table> <p>Uses For the temporary relief of minor aches and pains of muscles and joints due to: ■ arthritis ■ strains ■ bruises ■ sprains ■ simple backache</p> <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none">■ on wounds ■ irritated or damaged skin ■ sensitive skin■ with a heating pad ■ if pregnant■ with, or as the same time as, other external analgesic products■ if allergic to aspirin or salicylates■ if allergic to any ingredients of this product <p>When using this product</p> <ul style="list-style-type: none">■ avoid contact with the eyes ■ do not bandage tightly■ do not apply to wounds or damaged skin■ do not use 1 hour before or after bathing <p>MADE IN TAIWAN</p>	Active ingredients	Purpose	Methyl Salicylate 20.7%.....	External Analgesic	Menthol 15.6%.....	External Analgesic	Camphor 3.1%.....	External Analgesic
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HERBAL BALM

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82198-0007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	156 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	207 mg in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	31 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PETROLATUM (UNII: 4T6H12BN9U)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82198-0007-1	50 g in 1 JAR; Type 0: Not a Combination Product	10/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/01/2022	

Labeler - Big 5 Nutrition LLC (114574559)

Establishment

Name	Address	ID/FEI	Business Operations
Taiwan Shuenn-Ann Biotechnology Pharmaceutical Co., Ltd.		656348265	manufacture(82198-0007)

Revised: 11/2023

Big 5 Nutrition LLC