

BENGAY ULTRA STRENGTH NON-GREASY- camphor (synthetic), menthol, unspecified form, and methyl salicylate cream

Johnson & Johnson Consumer 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.

BENGAY® ULTRA STRENGTH NON-GREASY CREAM

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Camphor 4%	Topical analgesic
Menthol 10%	Topical analgesic
Methyl salicylate 30%	Topical analgesic

Use

temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have redness over affected area

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use only as directed
- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

store at 20° to 25°C (68° to 77°F)

Inactive ingredients

carbomer, disodium EDTA, glyceryl stearate SE, lanolin, polysorbate 80, potassium hydroxide, stearic acid, triethanolamine, water

Questions?

call **1-800-223-0182** (toll-free) **or 215-273-8755** (collect)

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

BENGAY®

TOPICAL ANALGESIC CREAM

**ULTRA
STRENGTH**

**With three ingredients for
powerful relief at the site of pain**

Camphor 4%

Menthol 10%

Methyl Salicylate 30%

NET WT 4 OZ (113 g)



EXP: _____
 LOT: _____
 0 74300 08194 6



BENGAY
 TOPICAL ANALGESIC CREAM

BENGAY
 ULTRA
 STRENGTH

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**ULTRA
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 With three
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 powerful relief
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BENGAY
 TOPICAL ANALGESIC CREAM

NET WT 4 OZ (113 g)



**ULTRA
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With three ingredients for
 powerful relief at the site of pain

- Camphor 4%
- Menthol 10%
- Methyl Salicylate 30%

NET WT 4 OZ (113 g)

BENGAY
 ULTRA
 STRENGTH



Provides deep, penetrating
 relief from muscle aches
 & joint pain

3

With three ingredients
 for powerful relief
 at the site of pain



Non-greasy

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 Skillman, NJ 08558
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 30042214
 www.bengay.com

<p>Drug Facts</p> <p>Active ingredients</p> <p>Camphor 4% Menthol 10% Methyl salicylate 30%</p> <p>Uses temporarily relieves the minor aches and pains of muscles and joints associated with: ■ simple headache ■ arthritis ■ strains ■ bruises ■ sprains</p> <p>Warnings For external use only.</p> <p>Do not use ■ on wounds or damaged skin ■ with a heating pad ■ on a child under 12 years of age with arthritis-like conditions Ask a doctor before use if you have redness over the affected area.</p> <p>When using this product ■ avoid contact with eyes or mucous membranes ■ do not use on large areas of skin</p>	<p>Purpose</p> <p>Topical analgesic Topical analgesic Topical analgesic</p>
<p>Drug Facts (continued)</p> <p>Drug use and ask a doctor if ■ condition worsens or symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ use only as directed ■ adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily ■ children under 12 years of age: ask a doctor</p> <p>Other information store at 20° to 25°C (68° to 77°F)</p> <p>Inactive ingredients camphor, disodium EDTA, glyceryl stearate SE, lanolin, polysorbate 80, potassium hydroxide, stearic acid, triethanolamine, water</p> <p>Questions? call 1-800-225-0142 (toll-free) or 215-273-8755 (collect)</p>	

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 camphor (synthetic), menthol, unspecified form, and methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0538
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	40 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	100 mg in 1 g
Methyl Salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Methyl Salicylate	300 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
Glyceryl Stearate SE (UNII: FCZ5MH785I)	
Lanolin (UNII: 7EV65EAW6H)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Potassium Hydroxide (UNII: WZH3C48M4T)	
Stearic Acid (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0538-2	1 in 1 CARTON	06/01/2018	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69968-0538-4	1 in 1 CARTON	06/01/2018	
2		113 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:69968-0538-5	2 in 1 CARTON	06/01/2018	
3		113 g in 1 TUBE; 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	06/01/2018	

Labeler - Johnson & Johnson Consumer Inc. (002347102)