

BELLADONA- methyl salicylate, menthol ointment
Miramar Cosmetics, Inc DBA Miramar Lab

Belladona

Drug Facts

Active Ingredients

Methyl Salicylate 10%
Menthol 3.5%

Purpose

Topical Analgesic

Uses:

*Helps relieve minor aches and pain of muscles, joints, strains, backache, sprains, and sport injuries.

Warnings:

For external use only.

Do not Use:

- If allergic to salicylates (including aspirin) without consulting a physician.
- On open wounds, damage or irritated skin, immediately after or before taking a shower.

Stop use and ask a Doctor: If conditions worsen, symptoms persist or skin irritations occurs.

When using this product: Avoid contact with eyes, lips and any mucous membranes.

Keep out of reach of children.

If swallowed get medical help. **Do not bandage.**

Directions:

Clean area before use.

Adults & Children 12 years of age or older: Apply to affected area no more than 3 times daily. Temporary burning may be felt when applied, but disappears with continued use.

Wash hands after used. If applying liniment to the hands wait 30 minutes before washing hands. Initial pain relief is noted within 1-2 weeks.

Children under 12 years: Consult a Physician before use.

Other Information:

Store at 15-25° C (59-77° F)

Inactive Ingredients:

White Petrolatum, Soybean Oil, Belladonna extract, Green MX-144A.

MADE IN USA

SATISFACTION GUARANTEED QUALITY

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Distributed by:

OTC & Quality Products

Orlando, FL 32837

InfoLine:

1-877-325-7887

www.otcqualityproducts.com

Packaging



BELLADONA

methyl salicylate, menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79974-209
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID -	METHYL SALICYLATE	10 g

UNII:O414PZ4LPZ)		METHYL SALICYLATE	in 100 g	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	3.5 g in 100 g	
Inactive Ingredients				
Ingredient Name		Strength		
WHITE PETROLATUM (UNII: B6E5W8RQJ4)				
SOYBEAN OIL (UNII: 241ATL177A)				
BELLADONNA LEAF (UNII: 6GZW20TIOI)				
D&C YELLOW NO. 11 (UNII: 44F3HYL954)				
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79974-209-05	150 g in 1 JAR; Type 0: Not a Combination Product	01/08/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	01/08/2024		

Labeler - Miramar Cosmetics, Inc DBA Miramar Lab (012873243)

Establishment

Name	Address	ID/FEI	Business Operations
Miramar Cosmetics, Inc DBA Miramar Lab		012873243	manufacture(79974-209)

Revised: 12/2023

Miramar Cosmetics, Inc DBA Miramar Lab