

BANALG- methyl salicylate lotion
Rebel Distributors Corp

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.

Banalg Drug Facts

Active ingredient

Methyl Salicylate 14.0%

Menthol 3.0%

Keep Out of Reach of Children

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis and rheumatism. Also good for simple backache, strains and sprains.

Warnings

Use only as directed. If pain persists more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult your physician immediately. Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes.

For external use only. Use only as directed. Do not apply to wounds, broken or irritated skin. Do not use with a heating pad. Do not bandage tightly.

If swallowed, induce vomiting and contact a physician or poison control center immediately.

Directions

Apply fast vanishing lotion with gentle massage to affected area not more than 3 to 4 times daily.

Package/Label Principal Display Panel

BANALG

methyl salicylate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-440(NDC:0456-0525)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	140 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
1,3-DIMETHYLBUTYL SALICYLATE (UNII: 47OL39K42M)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-440-02	60 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2007	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp