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 ach3es 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.

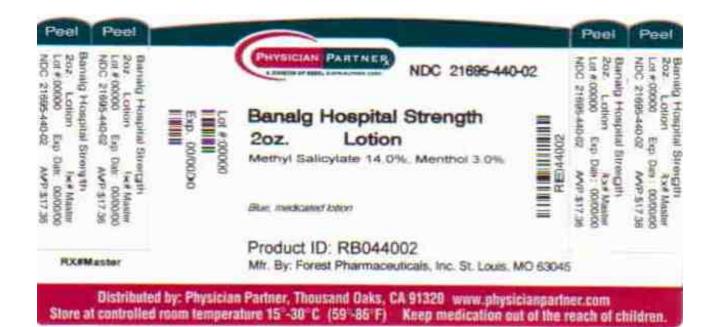
For external use only. Use only as directed. Do not apply to wounds, broken or irritated skin. Do not use with a heating pad. Do not bandage tightly.

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

WATER (UNII: 059QF0KO0R)

| 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: 470L39K42M) | | |

| 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 | 0 1/0 1/20 0 7 | |
| | | | |

Labeler - Rebel Distributors Corp (118802834)

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

Revised: 2/2011 Rebel Distributors Corp