

COATS ALOE ANALGESIC- methyl salicylate lotion
TYCHASIS CORPORATION

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.

COATS ALOE LINIMENT TOPICAL ANALGESIC

Active Ingredient:

Methyl Salicylate 10%

Purpose:

Topical analgesic, topical pain relief for intact skin.

Warnings:

- For external use only.
- Avoid contact with eyes or mucous membranes.
- Do not apply to wounds or damaged skin with a heating pad.
- Discontinue if irritation develops.
- Wash hands with soap and water after use.
- Do not bandage tightly.

Stop use if:

Stop use and ask a doctor if condition worsens, if symptoms persist more than 7 days, or if symptoms worsen within a few days.

Pregnant or breastfeeding:

Not recommended if you are pregnant or breastfeeding.

Consult your physician.

Indications and Usage:

Temporary relief of minor aches and pains of muscles and joints associated with:

- arthritis
- simple backaches
- strains
- sprains
- bruises

Do not use:

Do not use in combination with other topical analgesic products.

Keep out of reach of children:

Keep out of reach of children.

If accidentally ingested, seek medical help or contact poison control immediately.

Directions:

Adults and children 12 years of age and older: Apply to affected areas no more than 3-4 times daily.

Children under 12 years of age: Consult a physician.

Other information:

Store between 15 ° C and 30 ° C (59 ° F and 86 ° F).

Inactive Ingredients:

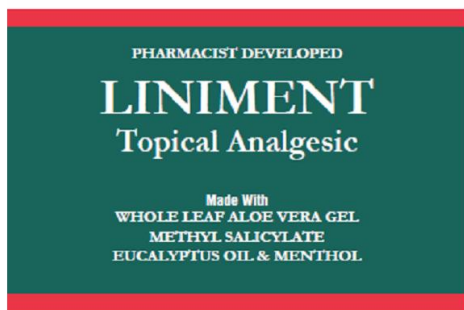
aloe barbadensis leaf juice, butylene glycol, caprylyl glycol, carbomer, cetearyl alcohol, cetyl alcohol, coconut oil, disodium EDTA, eucalyptus leaf oil, glyceryl stearate, isododecane, isopentylidol, menthol, pentylene glycol, petrolatum, phenoxyethanol, potassium palmitol hydrolyzed wheat protein, apricot kernel oil, sodium hydroxide, water

Questions:

Toll free number 888-650-0040

Package Label COATS ALOE LINIMENT

NDC #70211 704 08



8 fl Oz / 237 mL

| | |
|--|-------------------|
| Drug Facts | |
| Active ingredient Purpose | |
| Methyl Salicylate 10%..... | Topical Analgesic |
| Uses: temporary relief of minor aches, pains of muscles and joints associated with: arthritis, simple backaches, strains, sprains, bruises | |
| Warnings For external use only ■ do not use on children under 12 years with arthritis-like conditions ■ avoid getting into eyes or mucous membranes ■ do not apply to wounds or damaged skin with a heating pad ■ discontinue if irritation develops ■ do not use in combination with other analgesic products ■ wash hands with soap and water after use ■ do not bandage tightly | |
| Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days, or occur again within a few days. Not recommended if you are pregnant or breast-feeding. Consult your physician. | |
| Keep out of reach of children. If accidentally ingested seek medical help or contact Poison Control immediately. | |
| Directions | |
| ■ adults and children 12 years of age and older: apply to affected areas no more than 3 to 4 times daily | |
| ■ children under 12 years of age: consult a physician | |
| Other information | |
| Store between 15°C and 30°C (59°F and 86°F) | |
| Inactive ingredients water (aqua), aloe barbadensis leaf juice, isododecane, petrolatum, butylene glycol, pentylene glycol, cocos nucifera (coconut) oil, potassium palmitoyl hydrolyzed wheat protein, glyceryl stearate, cetylalcohol, carbomer, cetyl alcohol, eucalyptus globulus leaf oil, menthol, prunus armeniaca (apricot) kernel oil, disodium EDTA, caprylyl glycol, phenoxyethanol, isopentylidol, sodium hydroxide | |
| Questions or Comments? Call 1-888-650-0040 | |

Manufactured for:
Tychasis Corporation
Dallas, TX 75227
888-650-0040
www.coatsaloe.com

MADE IN U.S.A.



COATS ALOE ANALGESIC

methyl salicylate lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70211-704 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 10 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |

| | |
|---|--|
| HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL) | |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| APRICOT KERNEL OIL (UNII: 54JB35T06A) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ISOPENTYLDIOL (UNII: 19NOL5474Q) | |
| WATER (UNII: 059QF0K00R) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

Product Characteristics

| | | | |
|-----------------|---|---------------------|--|
| Color | white (can be off white due to natural variations of aloe vera) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70211-704-08 | 237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 11/02/2015 | |
| 2 | NDC:70211-704-33 | 976 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 11/02/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M017 | 11/02/2015 | |

Labeler - TYCHASIS CORPORATION (022731149)

Registrant - TYCHASIS CORPORATION (022731149)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| BIOMED LABORATORIES | | 055329696 | manufacture(70211-704) |