

**COATS ALOE ANALGESIC- methyl salicylate, aloe 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.*

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**COATS ALOE LINIMENT**

**ACTIVE INGREDIENT**

METHYL SALICYLATE 10% TOPICAL ANALGESIC

MENTHOL 1%

**USE**

TEMPORARY RELIEF OF MINOR ACHES AND PAINS OF MUSCLES AND JOINTS  
ASSOCIATED WITH: ARTHRITIS, SIMPLE BACKACHES, STRAINS, SPRAINS, BRUISES

**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

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 DOCTOR IF CONDITION WORSENS IF SYMPTOMS PERSIST MORE  
THAN 7 DAYS, OR IF SYMPTOMS WORSEN WITHIN A FEW DAYS.

NOT RECOMMENDED IF YOU ARE PREGNANT OR BREASTFEEDING. 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  
3-4 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, Cocos Nucifera (Coconut) Oil, Disodium EDTA, Eucalyptus Globulus Leaf Oil, Glyceryl Stearate, Isododecane, Isopentylidiol, Menthol, Pentylene Glycol, Petrolatum, Phenoxyethanol, Potassium palmitol hydrolyzed wheat protein, Prunus Armeniaca (Apricot Kernel Oil), Sodium Hydroxide, Water (Aqua)

## KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If accidentally ingested seek medical help or contact Poison Control immediately.

## PACKAGE LABEL COATS ALOE LINIMENT 8 OZ

<p>NDC #58826 704 08</p>  <p>PHARMACIST DEVELOPED</p> <h1>LINIMENT</h1> <p>Topical Analgesic</p> <p>Made With WHOLE LEAF ALOE VERA GEL METHYL SALICYLATE EUCALYPTUS OIL &amp; MENTHOL</p> <p>8 fl Oz / 237 mL</p>	<table border="1"><tr><td colspan="2"><b>Drug Facts</b></td></tr><tr><td><b>Active ingredient</b> .....</td><td><b>Purpose</b></td></tr><tr><td>Methyl Salicylate 10% .....</td><td>Topical Analgesic</td></tr><tr><td colspan="2"><b>Uses:</b> temporary relief of minor aches, pains of muscles and joints associated with: arthritis, simple backaches, strains, sprains, bruises</td></tr><tr><td colspan="2"><b>Warnings</b> 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</td></tr><tr><td colspan="2"><b>Stop use and ask a doctor if</b> ■ condition worsens ■ symptoms persist for more than 7 days, or occur again within a few days. <b>Not recommended if you are pregnant or breast-feeding.</b> Consult your physician.</td></tr><tr><td colspan="2"><b>Keep out of reach of children.</b> If accidentally ingested seek medical help or contact Poison Control immediately.</td></tr><tr><td colspan="2"><b>Directions</b></td></tr><tr><td colspan="2">■ adults and children 12 years of age and older: apply to affected areas no more than 3 to 4 times daily</td></tr><tr><td colspan="2">■ children under 12 years of age: consult a physician</td></tr><tr><td colspan="2"><b>Other information</b></td></tr><tr><td colspan="2">Store between 15°C and 30°C (59°F and 86°F)</td></tr><tr><td colspan="2"><b>Inactive ingredients</b> water (aqua), aloe barbadensis leaf juice, isododecane, petrolatum, butylene glycol, pentylene glycol, cocos nucifera (coconut) oil, potassium palmitoyl hydrolyzed wheat protein, glyceryl stearate, cetearyl alcohol, carbomer, cetyl alcohol, eucalyptus globulus leaf oil, menthol, prunus armeniaca (apricot) kernel oil, disodium EDTA, caprylyl glycol, phenoxyethanol, isopentylidiol, sodium hydroxide</td></tr><tr><td colspan="2"><b>Questions or Comments?</b> Call 1-888-650-0040</td></tr></table> <p>Manufactured for: Tychasis Corporation Dallas, TX 75227 888-650-0040 www.tychasis.com</p> <p>MADE IN U.S.A.</p>  <p>7 32295 70408 9</p>	<b>Drug Facts</b>		<b>Active ingredient</b> .....	<b>Purpose</b>	Methyl Salicylate 10% .....	Topical Analgesic	<b>Uses:</b> temporary relief of minor aches, pains of muscles and joints associated with: arthritis, simple backaches, strains, sprains, bruises		<b>Warnings</b> 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		<b>Stop use and ask a doctor if</b> ■ condition worsens ■ symptoms persist for more than 7 days, or occur again within a few days. <b>Not recommended if you are pregnant or breast-feeding.</b> Consult your physician.		<b>Keep out of reach of children.</b> If accidentally ingested seek medical help or contact Poison Control immediately.		<b>Directions</b>		■ 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		<b>Other information</b>		Store between 15°C and 30°C (59°F and 86°F)		<b>Inactive ingredients</b> water (aqua), aloe barbadensis leaf juice, isododecane, petrolatum, butylene glycol, pentylene glycol, cocos nucifera (coconut) oil, potassium palmitoyl hydrolyzed wheat protein, glyceryl stearate, cetearyl alcohol, carbomer, cetyl alcohol, eucalyptus globulus leaf oil, menthol, prunus armeniaca (apricot) kernel oil, disodium EDTA, caprylyl glycol, phenoxyethanol, isopentylidiol, sodium hydroxide		<b>Questions or Comments?</b> Call 1-888-650-0040	
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## QUESTIONS

888-650-0040

customerservice@coatsaloevera.com

# COATS ALOE ANALGESIC

methyl salicylate, aloe lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58826-704
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 1 g

## Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ISODODECANE (UNII: A8289P68Y2)	
ISOPENTYLDIOL (UNII: 19NOL5474Q)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
PRUNUS ARMENIACA SEED (UNII: 75356789IW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MENTHOL (UNII: L7T10EIP3A)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	

## Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58826-704-08	237 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/29/2015	
2	NDC:58826-704-33	976 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/29/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/29/2015	

**Labeler** - TYCHASIS CORPORATION (022731149)

Revised: 10/2015

TYCHASIS CORPORATION