

**COATS ALOE- lotions, oils, powders, and creams 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 LOTION 85%

Active Ingredient

Allantoin 0.5%

Purpose

Skin protectant

Warnings

For external use only.

When using this product do not get into eyes.

Stop use and ask a doctor if:

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Do not use on deep puncture wounds, animals bites, serious burns.

Uses

Temporarily protects minor

- cuts
- scrapes
- burns

Helps prevent and temporarily protects and helps relieve chaffed, chapped or cracked skin.

Helps prevent and protect from the drying effects of wind and cold weather.

Keep out of reach of children

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply as needed.

Inactive Ingredients

aloe barbadensis leaf juice, ethylhexyl palmitate, glycerin, methyl gluceth-20, glyceryl stearate, C12-15 alkyl benzoate, water, cetyl alcohol, triethanolamine, stearic acid, ethylhexyl stearate, diethylhexyl adipate, retinyl palmitate, tocopheryl acetate, laureth-4, laureth-23, carbomer, diazolidinyl urea,

methylparaben, propylparaben

COATS ALOE LOTION 8 OZ

NDC #58826 702 08



8 fl Oz / 237 mL

Drug Facts	
Active Ingredients	Purpose
Allantoin 0.5%	Skin Protectant
Uses:	
Temporarily protects minor cuts, scrapes and burns. Helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin. Helps prevent and protect from the drying effects of wind and cold weather.	
Warnings:	
For external use only.	
When using this product do not get into eyes.	
Stop use and ask a doctor if:	
■ condition worsens ■ if symptoms last more than 7 days, or clear up and occur again within a few days.	
Do not use on deep or puncture wounds, animal bites, serious burns.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions: Apply as needed.	
Inactive Ingredients: Aloe Barbadosensis Leaf Juice, Ethylhexyl Palmitate, Glycerin, Methylgluceth-20, Glyceryl Stearate, C12-15 Alkyl Benzoate, Water, Cetyl Alcohol, Triethanolamine, Stearic Acid, Ethylhexyl Stearate, Diethylhexyladipate, Fitolinyl Palmitate, Tocopheryl Acetate, Laureth-4, Laureth-23, Carbomer, Diazolidinyl Urea, Methylparaben, Propylparaben	
Other Information: Store at room temperature, between 59-86°F (15-30°C). Store away from heat.	
Questions or Comments: 1-888-650-0040	

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



MADE IN U.S.A.

COATS ALOE

lotions, oils, powders, and creams lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58826-702
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

BOROGLYCERIN (UNII: U3LMU4AN21)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIETHYLHEXYL ADIPATE (UNII: MBY1SL921L)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LAURETH-4 (UNII: 6HQ855798J)	
LAURETH-23 (UNII: N72LMW566G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58826-702-08	237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/10/2015	
2	NDC:58826-702-33	976 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/10/2015	
3	NDC:58826-702-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/10/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/10/2015	

Labeler - TYCHASIS CORPORATION (022731149)

Registrant - TYCHASIS CORPORATION (022731149)

Establishment

Name	Address	ID/FEI	Business Operations
BIOMED LABORATORIES		055329696	manufacture(58826-702)

