

**COATS ALOE- allantoin 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**

**Active Ingredient:**

Allantoin 0.5%

**Purpose:**

Skin Protectant.

**Warnings:**

For external use only.

Do not get into eyes.

**Stop use if:**

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.

**Uses:**

Temporarily protects minor:

- cuts
- scapes
- 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.

**Caution:**

Do not use on deep 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:

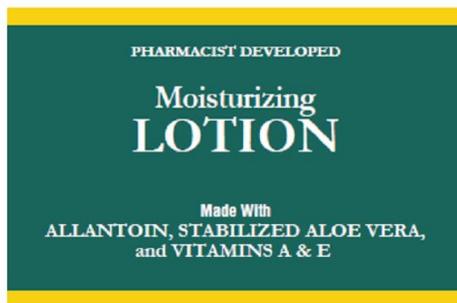
aloe barbanesis leaf juice, ethylhexyl palmitate, glycerin, methylgluceth-20, glyceryl stearate, C12-15 alkyl benzoate, water, cetyl alcohol, triethanolamine, stearic acid, ethylhexyl stearate, diethylhexyl adipate, retinyl palmitate, tocopheryl acetate, laureth-4, laureth-23, carbomer, diazolidinyl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

## Questions:

Toll free 888-650-0040

## Package label COATS ALOE LOTION

NDC #70211 702 08



8 fl Oz / 237 mL

Drug Facts	
<b>Active Ingredients</b> .....	<b>Purpose</b>
Allantoin 0.5% .....	Skin Protectant
<b>Uses:</b>	
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.	
<b>Warnings:</b>	
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.	
<b>Directions:</b> Apply as needed.	
<b>Inactive Ingredients:</b> Aloe Barbadensis Leaf Juice, Ethylhexyl Palmitate, Glycerin, Methylgluceth-20, Glyceryl Stearate, C12-15 Alkyl Benzoate, Water, Cetyl Alcohol, Triethanolamine, Stearic Acid, Ethylhexyl Stearate, Diethylhexyladipate, Retinyl Palmitate, Tocopheryl Acetate, Laureth-4, Laureth-23, Carbomer, Diazolidinyl Urea, Methylparaben, Propylparaben	
<b>Other Information:</b> Store at room temperature, between 59-86°F (15-30°C). Store away from heat.	
<b>Questions or Comments:</b> 1-888-650-0040	

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

MADE IN U.S.A.



**COATS ALOE**

allantoin lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70211-702
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ALKYL (C12-15) 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)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BORGLYCERIN (UNII: U3LMU4AN21)	

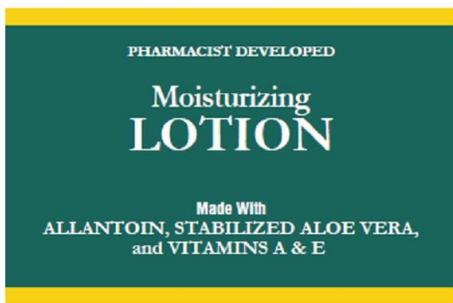
**Product Characteristics**

<b>Color</b>	white (may be slightly off white due to natural variations of aloe vera)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70211-702-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/02/2015	
2	NDC:70211-702-08	237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/02/2015	
3	NDC:70211-702-33	976 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/02/2015	

NDC #70211 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 chapped, 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 Barbadosia Leaf Juice, Ethylhexyl Palmitate, Glycerin, Methylgluceth-20, Glycerol Stearate, C12-15 Alkyl Benzoate, Water, Cetyl Alcohol, Triethanolamine, Stearic Acid, Ethylhexyl Stearate, Diethylhexyladipate, Retinyl 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.coataloe.com



MADE IN U.S.A.

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/02/2015	

**Labeler** - TYCHASIS CORPORATION (022731149)

**Registrant** - TYCHASIS CORPORATION (022731149)

**Establishment**

Name	Address	ID/FEI	Business Operations
BIOMED LABORATORIES		055329696	manufacture(70211-702)

Revised: 1/2023

TYCHASIS CORPORATION