

COATS ALOE- allantoin cream
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 CREME

Active Ingredient:

Allantoin 0.5%

Purpose:

Skin Protectant

Warnings:

For external use only.

Do not get into eyes.

Stop use and ask doctor 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.

Indications and Usage:

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.

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 right away.

Directions:

Apply as needed.

Inactive Ingredients:

water, aloe barbadensis leaf juice, caprylic/capric triglyceride, cetyl alcohol, potassium palmityl hydrolyzed wheat protein, glyceryl stearate, pentylene glycol, butyrospermum parkii (shea) butter, C12-15 alkyl benzoate, glycerin, beta-glucan, sodium hyaluronate, glyceryl stearate SE, cetareth-20, dehydroacetic acid, benzyl alcohol

Questions:

Toll free number 888-650-0040

Package Label COATS ALOE CREME

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. Do not use on deep or puncture wounds, animal bites, serious burns. 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.
Drug Facts (continued)	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
Directions: Apply as needed.	
Inactive Ingredients: Water, Aloe Barbadensis Leaf Juice, Pentylene Glycol, Sodium Hyaluronate, Potassium Palmitoyl Hydrolyzed Wheat Protein, Glyceryl Stearate, Cetyl Alcohol, Cetareth-20, Glyceryl Stearate SE, Caprylic/Capric Triglyceride, C 12-15 Alkyl Benzoate, Butyrospermum Parkii (Shea) Butter, Glycerin, Dehydroacetic Acid, Benzyl Alcohol, Beta-glucan	
QUESTIONS OR COMMENTS: 1-888-650-0040	

COATS ALOE

allantoin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70211-703
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM PALMITATE (UNII: KTC40CLC68)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

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:70211-703-04	118 g in 1 JAR; Type 0: Not a Combination Product	11/02/2015	
2	NDC:70211-703-16	454 g in 1 JAR; Type 0: Not a Combination Product	11/02/2015	

Mfg. for Tychasis Corp. Chiles, TX 75627
www.coachs.com MADE IN U.S.A.
7 32295 70304 4

NDC #70211 703 04



PHARMACIST DEVELOPED • FRAGRANCE FREE • PARABEN FREE
CREME
Made With
ALLANTOIN, STABILIZED ALOE VERA & SHEA BUTTER

Net wt 4 Oz / 118 g

Drug Facts		Drug Facts (continued)
Active Ingredients Allantoin 0.5%	Purpose Skin Protectant	Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.
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.		Directions: Apply as needed.
Warnings: For external use only. When using this product do not get into eyes. Do not use on deep or puncture wounds, animal bites, serious burns. 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.		Inactive Ingredients: Water, Aloe Barbadensis Leaf Juice, Pentylene Glycol, Sodium Hyaluronate, Potassium Palmitoyl Hydrolyzed Wheat Protein, Glyceryl Stearate, Cetearyl Alcohol, Ceteareth-20, Glyceryl Stearate SE, Caprylic/Capric Triglyceride, C-12-15 Alkyl Benzoate, Butyrospermum Parkii (Shea) Butter, Glycerin, Dihydroxyacetic Acid, Benzyl Alcohol, Beta-glucan
		QUESTIONS OR COMMENTS: 1-888-850-0040

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(70211-703)

Revised: 1/2023

TYCHASIS CORPORATION