

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%

Uses:

Skin protectant

Warnings

For external use only.

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.

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.

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.

Directions:

Apply as needed.

Inactive Ingredients:

water, aloe barbadensis leaf juice, caprylic/capric triglyceride, cetyl alcohol, postassium palmitoyl hydrolyzed wheat protein, glycerol stearate, pentylene glycol, butyrospermum parkii (shea) butter, c12-15 alkyl benzoate, glycerin, beta-glucan, sodium hyaluronate, glyceryl stearate SE, cetearath-20, dehydroacetic acid, benzyl alcohol

Questions:

Toll free number 888-650-0040

Package Label: COATS ALOE CREME 4 OZ

Drug Facts

Active Ingredients Allantoin 0.5%	Purpose Skin Protectant
Use: 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)

Directions: Apply as needed.
Inactive Ingredients: Water, Aloe Barbadensis Leaf Juice, Pentylene Glycol, Sodium Hyaluronate, Potassium Palmitoyl Hydrolyzed Wheat Protein, Glyceryl Stearate, Cetylal Alcohol, Cetearath-20, Glycerin, 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:58826-703
Route of Administration	TOPICAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
WATER (UNII: 059QF0K00R)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
POTASSIUM PALMITATE (UNII: KTC40CLC68)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SHEA BUTTER (UNII: K49155WL9Y)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Product Characteristics

Color	white (thick white creme, can sometimes be off-white due to natural characteristics of aloe vera)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58826-703-04	118 g in 1 JAR; Type 0: Not a Combination Product	10/10/2015	
2	NDC:58826-703-16	454 g in 1 JAR; 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(58826-703)