COATS ALOE- allantoin jelly 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 GELLY 90%

Active Ingredient

Allantoin 0.5%

Purpose

Skin protectant.

Warnings

For external use only.

When using this product do not get into eyes.

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.

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

aloe barbadenesis leaf juice, water, butylene glycol, carbomer, triethanolamine, xanthum gum, panthenol, glycerin, chlorphensin, potassium sorbate, sodium benzoate, beta-glucan

Directions

Apply as needed

Use

Apply as needed

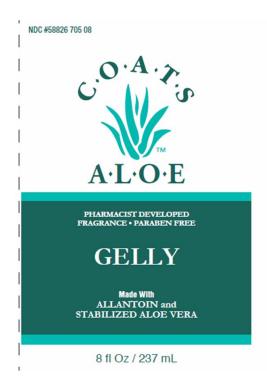
Keep out of reach of children

Keep out of reach of children.

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

Do not use on deep puncture wounds, animal bits, serious burns.

COATS ALOE GELLY 8 OZ





MADE IN U.S.A.

COATS ALOE

allantoin jelly

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58826-705	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALLANTO IN (UNII: 344S277G0Z) (ALLANTO IN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 mL		

Inactive Ingredients				
Ingredient Name	Strength			
CHLO RPHENES IN (UNII: 1670 DAL4SZ)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Product Characteristics			
Color	yellow (CLEAR TO YELLOW, COLOR CAN VARY DUE TO NATURAL VARIATIONS OF ALOE VERA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

1	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:58826-705	237 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(58826-705)	

Revised: 10/2015 TYCHASIS CORPORATION