

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 barbadensis 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 bites, serious burns.

COATS ALOE GELLY 8 OZ

NDC #58826 705 08



PHARMACIST DEVELOPED
FRAGRANCE • PARABEN FREE

GELLY

Made With
ALLANTOIN and
STABILIZED ALOE VERA

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: Water, Aloe Barbadosis Leaf Juice, Butylene Glycol, Carbomer, Triethanolamine, Xanthan Gum, Panthenol, Glycerin, Chlorphenesin, Potassium Sorbate, Sodium Benzoate, Beta-glucan

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.



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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
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58826-705-08	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)