

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

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
- 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, animals 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 barbadensis leaf juice, water, butylene glycol, carbomer, triethanolamine, xanthan gum, panthenol, glycerin, chlorphenesin, potassium sorbate, sodium benzoate, beta-glucan

Questions:

Toll free 888-650-0040

Package Label COATS ALOE GELLY 8 OZ

NDC #70211 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:

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Helps prevent and temporarily protects and helps relieve chafed, chapped or cracked skin.
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Directions: Apply as needed.

Inactive Ingredients: Water, Aloe Barbadensis 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.coatsaloe.com

MADE IN U.S.A.



COATS ALOE

allantoin jelly

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70211-705 |
| 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 |
|--------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C00X) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| PANTHENOL (UNII: WW9CM0067Z) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| CHLORPHENESIN (UNII: I670DAL4SZ) | |

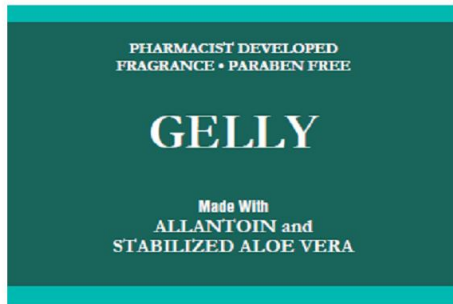
Product Characteristics

| | | | |
|-----------------|---|---------------------|--|
| Color | yellow (CLEAR TO OFF YELLOW 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:70211-705-08 | 237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 11/02/2015 | |

NDC #70211 705 08



8 fl Oz / 237 mL

Drug Facts

Active Ingredients **Purpose**
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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(70211-705) |

Revised: 1/2023

TYCHASIS CORPORATION