ASTRINGENT- calcium acetate monohydrate and aluminum sulfate tetradecahydrate powder, for solution Granulation Technology, Inc.

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.

Astringent Solution

Drug Facts

Active ingredients (in each packet)	Purpose	
Aluminum sulfate tetradecahydrate, 1347 mg	Astringent *	
Calcium acetate monohydrate, 952 mg	Astringent	

^{*} When combined together in water, these ingredients form the active ingredient aluminum acetate. See Directions.

Uses

temporarily relieves minor skin irritations due to:

- poison ivy
- poison oak
- poison sumac
- insect bites
- athlete's foot
- rashes caused by soaps, detergents, cosmetics, or jewelry

Warnings

For external use only

When using this product

- avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- do not cover compress or wet dressing with plastic to prevent evaporation
- in some skin conditions, soaking too long may overdry

Stop use and ask a doctorif condition worsens or symptoms persist for more than 7 days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- dissolve 1 to 3 packets in a pint (16 oz) of cool or warm water
- stir until fully dissolved; do not strain or filter. The resulting mixture contains 0.16%

(1 packet), 0.32% (2 packets), or 0.48% (3 packets) aluminum acetate and is ready for use.

For use as a soak:

- soak affected area for 15 to 30 minutes as needed, or as directed by a doctor
- repeat 3 times a day or as directed by a doctor
- discard solution after each use

For use as a compress or wet dressing:

- soak a clean, soft cloth in the solution
- apply cloth loosely to affected area for 15 to 30 minutes
- repeat as needed or as directed by a doctor
- discard solution after each use

Other information

protect from excessive heat

Inactive ingredients

Dextrin

Questions or comments?

1-973-276-0740

Manufactured by:

Granulation Technology, Inc.

Fairfield, NJ 07004

Made In USA

PRINCIPAL DISPLAY PANEL - 2299 mg Packet Carton

NDC 63561-0178-2

ALUMINUM SULFATE TETRADECAHYDRATE / CALCIUM ACETATE MONOHYDRATE ASTRINGENT SOLUTION

Soothing, Effective Relief of Minor Skin Irritations due to:

Poison Ivy Athlete's Foot Insect Bites Rashes

Compares to the Active Ingredients in Domeboro ®

Granulation Technology, Inc.

12 **POWDER**PACKETS

Side Seam - - LEBG1034Z Questions or comments? 1-973-276-0740 12 POWDER PACKETS Inactive ingredients dextrin Other information protect from excessive heat Directions - dissolve 1.0.3 packets in a pint (16 oz) of cool or warm water - dissolve 1.0.3 packets in a pint (16 oz) of cool or warm water - sur until high (dissolved; do not strain or filler. The resulting mixture contains 0.16% (1 packet). For use as a soak: - coak sidected area for 15 to 30 minutes as needed, or as directed by a doctor - coak a coultion after each use - dissand coultion after each use - dissand celens, out cloth in the southor - spayl coultin cosely to affected area for 15 to 30 minutes - repeat as needed or as directed by a doctor - spayl coult locasily to affected area for 15 to 30 minutes - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor - repeat as needed or as directed by a doctor Granulation Technology, Inc. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Stop use and ask a doctor if condition worsens or symptoms persist for more than 7 days When using this product - avoid contact occurs, rinse thoroughly with water, - do not cover compress or wet dressing with plastic to prevent evaporation - in some skin conditions, soaking too long may overdry **ASTRINGENT SOLUTION** Uses temporarily relieves minor skin inflations due to: • poison ivy • poison oak • poison sumac • insect bites • athlete's foot • rashes caused by soaps, detergents, cosmetics, or jewelry FB0084 Rev. 09/23 skin irritations. has been trusted to help relieve minor Astringent Solution provides soothing, effective relief of minor skin irritations. For over 50 years, Astringent Solution has been strated to help relieve minor. Purpose Astringent* Active ingredients (in each packet) รมาย คนเล **АSTRINGENT SOLUTION** ASTRINGENT SOLUTION 12 POWDER PACKETS NDC 63561-0178-2 **ASTRINGENT SOLUTION** ALUMINUM SULFATE TETRADECAHYDRATE/ CALCIUM ACETATE MONOHYDRATE ASTRINGENT SOLUTION Soothing, Effective Relief of Minor Skin Irritations due to: **Poison Ivy** Athlete's Foot **Insect Bites** 12 POWDER PACKETS **Rashes**

ASTRINGENT SOLUTION

Granulation Technology, Inc.

12 POWDER PACKETS

12 POWDER PACKETS

ASTRINGENT

calcium acetate monohydrate and aluminum sulfate tetradecahydrate powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63561-0178
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CALCIUM ACETATE MONOHYDRATE (UNII: 7ZA48GIM5H) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM ACETATE MONOHYDRATE	952 mg in 2299 mg		
ALUMINUM SULFATE TETRADECAHYDRATE (UNII: E3UT66504P) (ALUMINUM CATION - UNII:3XHB1D032B)	ALUMINUM SULFATE TETRADECAHYDRATE	1347 mg in 2299 mg		

Inactive Ingredients	
Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63561- 0178-2	12 in 1 CARTON	10/05/2023		
1	NDC:63561- 0178-1	2299 mg in 1 PACKET; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part347	10/05/2023		

Labeler - Granulation Technology, Inc. (847132193)

Registrant - Granulation Technology, Inc. (847132193)

Establishment				
Name	Address	ID/FEI	Business Operations	
Granulation Technology, Inc.		847132193	manufacture(63561-0178)	

Revised: 10/2023 Granulation Technology, Inc.