ASTRINGENT- calcium acetate monohydrate and aluminum sulfate tetradecahydrate powder, for solution

TAGI Pharma 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:

- poisonivy
- 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 doctor if 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?

1-855-225-8244

Manufactured by: Epic Pharma, LLC Laurelton, NY 11413

Distributed by: TAGI Pharma South Beloit, IL 61080

PRINCIPAL DISPLAY PANEL - 2299 mg Packet Carton

NDC 51224-162-12

ALUMINUM SULFATE TETRADECAHYDRATE / CALCIUM ACETATE MONOHYDRATE $\boldsymbol{\mathsf{ASTRINGENT}}$ 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®

tagiPHARMA

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:51224-162
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
icodextrin (UNII: 2NX48Z0A9G)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51224-162-24	12 in 1 CARTON	06/01/2012	
1	NDC:51224-162-12	12 in 1 BOX		
1	NDC:51224-162-99	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	06/01/2012	

Labeler - TAGI Pharma Inc. (963322560)

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