

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

First Nation Group

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.

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

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

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% (3packets) 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.

Protect from excessive heat.

Dextrin

1-855-221-5332

Distributed by:

First Nation Group, LLC

Niceville, FL 32578



ASTRINGENT SOLUTION

aluminum sulfate tetradecahydrate, calcium acetate monohydrate powder, for solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:81469-999

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ICODextrin (UNII: 2NX48Z0A9G)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81469-999-12	12 in 1 BOX	09/27/2023	
1	NDC:81469-999-01	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	09/27/2023	

Labeler - First Nation Group (078875731)

Revised: 9/2023

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