

NIACINAMIDE 4% / TACROLIMUS 0.1% - niacinamide 4% / tacrolimus 0.1% ointment
Sincerus Florida, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

NIACINAMIDE 4% / TACROLIMUS 0.1%

Directions for use



...ing FACTOLIMUS cream... should be avoided, and application... ment with atopic dermatitis. ROLIMUS Creams/Ointments is not indicated for use in children less than 2 years of age. Rolimus should not be used in immunocompromised adults and children.

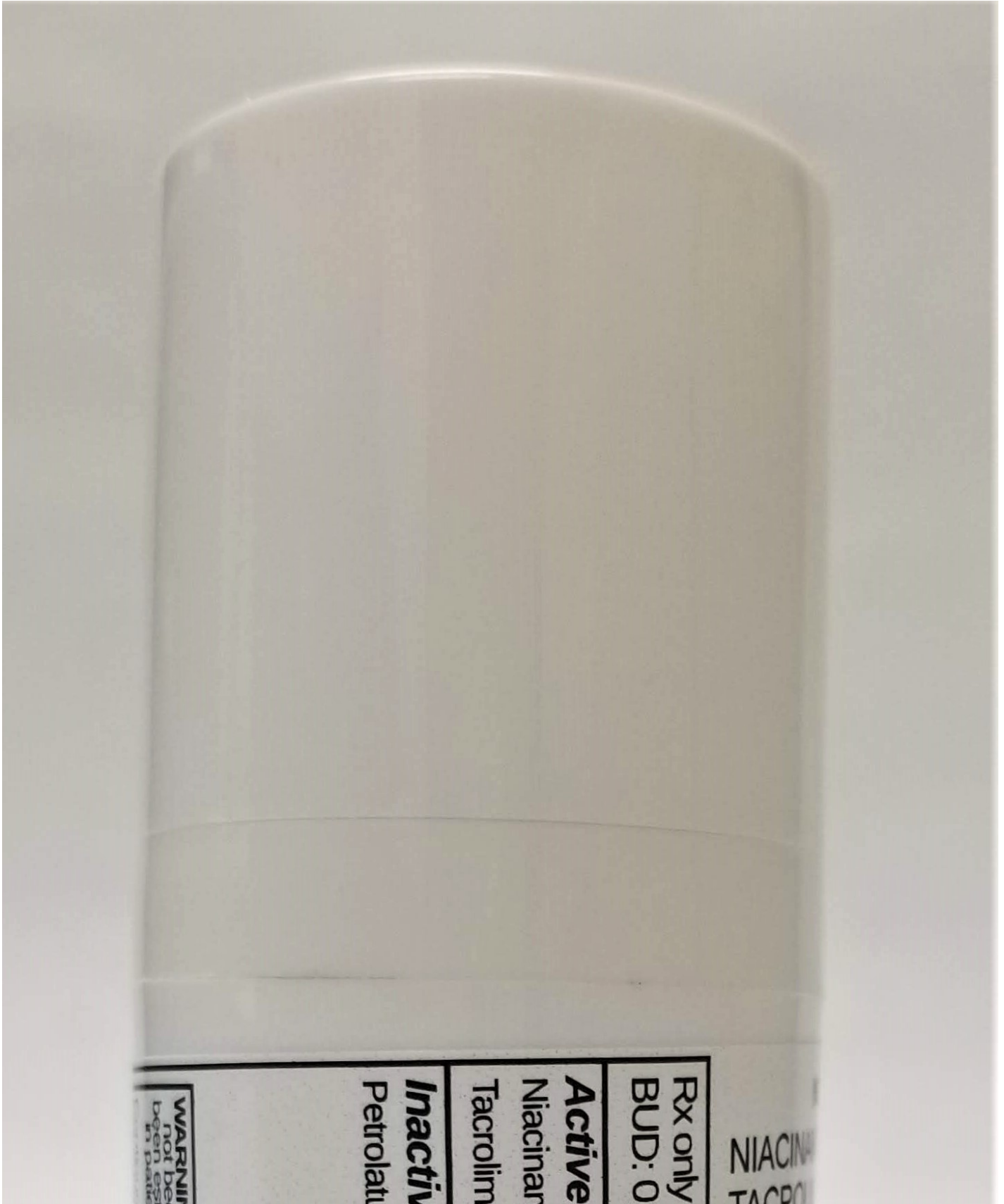
Directions for use

Directed by Physician.
Apply topically. For external use only. Wash hands after use.
Store at controlled room temperature (20-25C).

Genus Florida, LLC (800) 604-5032
5 W McNab Rd, Pompano Beach, FL 33069
Report suspected adverse reactions, contact
Genus Florida, LLC at (800) 604-5032, or FDA
www.FDA.gov/MedWatch or (800) FDA-1088.
Office use only. Not for resale.



Active, inactive



TACROLIMUS
USP 0.1%
OINTMENT

SINO

1/01/1970

Lot: 101018ABCDEFGHI@1

MFG: 01/01/1970

Ingredients

Niacinamide USP 4%
Tacrolimus Monohydrate USP 0.1%

Other ingredients

..... 95.9%

WARNING: Long-term safety of topical calcineurin inhibitors has not been established. Although a causal relationship has not been established, rare cases of malignancy have been reported. Use of this product should be limited to the treatment of the conditions for which it is indicated.

NDC 72934-5159-2 NIACINAMIDE USP 4% / TACROLIMUS USP 0.1%.
Ointment 30gm



NDC 72934-5159-2

**NIACINAMIDE USP 4%
TACROLIMUS MONOHYDRATE
USP 0.1%
OINTMENT 30gm**

Rx only
BUD: 01/01/1970

Lot



NIACINAMIDE 4% / TACROLIMUS 0.1%

niacinamide 4% / tacrolimus 0.1% ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72934-5159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TACROLIMUS (UNII: WM0HAQ4WNM) (TACROLIMUS ANHYDROUS - UNII:Y5L2157C4J)	TACROLIMUS ANHYDROUS	0.1 g in 100 g
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	4 g in 100 g

Product Characteristics

Color	white (CLEAR OINTMENT)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-5159-2	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2019	

Labeler - Sincerus Florida, LLC (080105003)

Establishment

Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-5159)

Revised: 4/2019

Sincerus Florida, LLC