

NIACINAMIDE 4% / TACROLIMUS 0.03% - niacinamide 4% / tacrolimus 0.03% 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 0.03%

Directions for use



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As directed by Physician.

Apply topically. For external use only. Wash hands after use.

Store at controlled room temperature (20-25C).

Sincerus Florida, LLC

(800) 604-5032

3265 W McNab Rd, Pompano Beach, FL 33069

To report suspected adverse reactions, contact

Sincerus Florida, LLC at (800) 604-5032, or FDA
at www.FDA.gov/MedWatch or (800) FDA-1088.

Office use only. Not for resale.



Sincerus Florida, LLC. Adverse reactions



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Active, inactive



NIACINAMIDE
TACROLIMUS
USP 0.03%
OINTMENT

SINCE

Rx only
BUD: 01/01/1970

Lot: 1010119ABCFGH@1
MFG: 01/01/1970

Active ingredients

Niacinamide USP	4%
Tacrolimus Monohydrate USP	0.03%

Inactive ingredients

Petrolatum	95.97%
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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 in patients treated with topical calcineurin inhibitors. Use only as directed.



NDC 72934- 5158-2 NIACINAMIDE USP 4% / TACROLIMUS USP 0.03%. Ointment 30gm.





NIACINAMIDE 4% / TACROLIMUS 0.03%

niacinamide 4% / tacrolimus 0.03% ointment

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:72934-5158

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
TACROLIMUS (UNII: WM0HAQ4WNM) (TACROLIMUS ANHYDROUS - UNII:Y5L2157C4J)		TACROLIMUS ANHYDROUS	0.03 g in 100 g	
NIACINAMIDE (UNII: 25X51I8 RD4) (NIACINAMIDE - UNII:25X51I8 RD4)		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:72934-5158-2	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/17/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		05/17/2019		

Labeler - Sincerus Florida, LLC (080105003)

Establishment			
Name	Address	ID/FEI	Business Operations
Sincerus Florida, LLC		080105003	manufacture(72934-5158)