TACROLIMUS 0.1% IN PSEUDOCATALASE- tacrolimus 0.1% in pseudocatalase cream
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.

TACROLIMUS 0.1% IN PSEUDOCATALASE

Directions for use

Sincerus Florida, LLC adverse reactions.

Continuous long-term use of [illegible]
including TACROLIMUS cream [illegible]
should be avoided, and application limited to areas of
involvement with atopic dermatitis.
TACROLIMUS Creams/Ointments is not indicated for use in
children less than 2 years of age.
Tacrolimus should not be used in immunocompromised adults
and children.

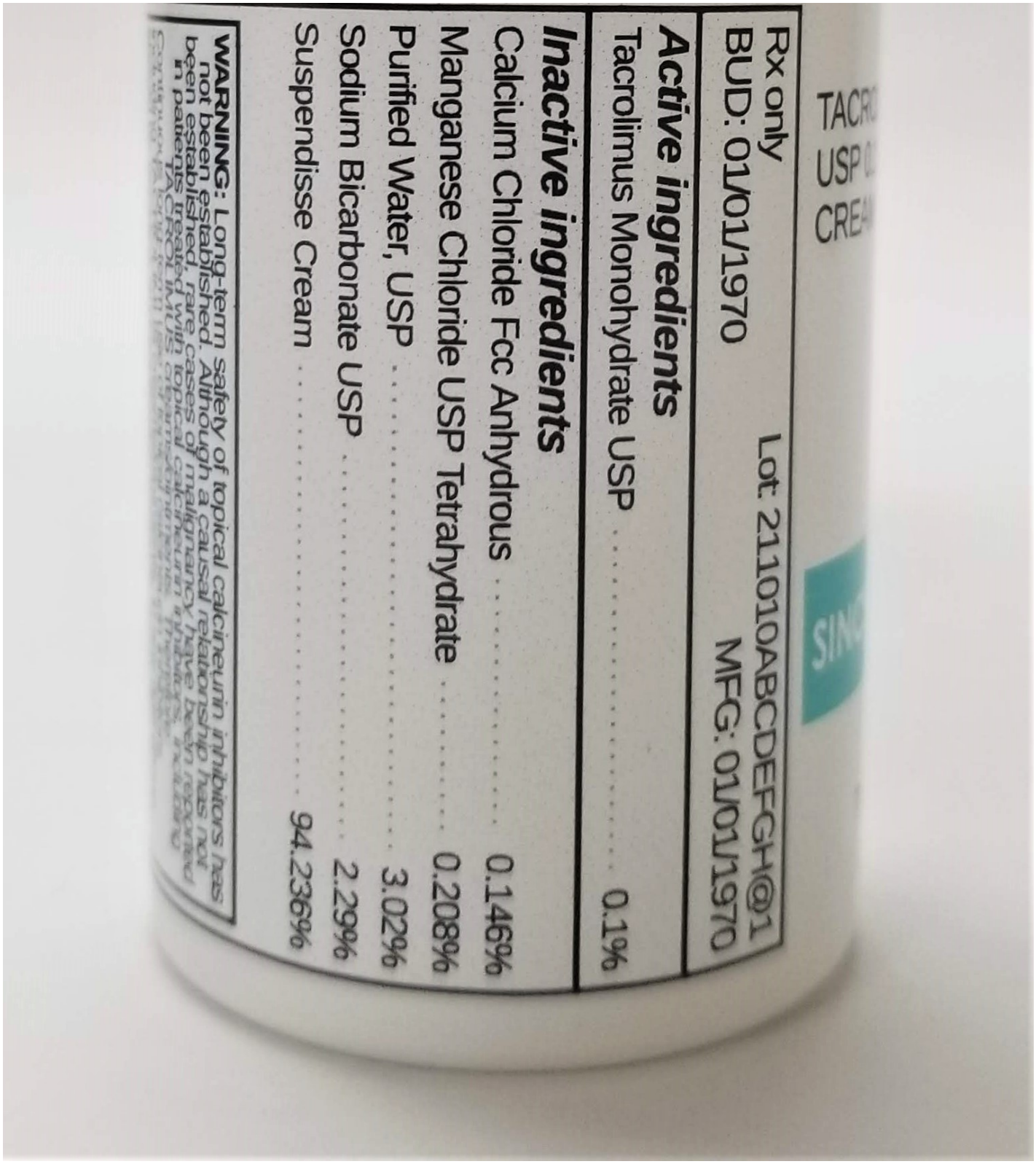
Directions for use

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

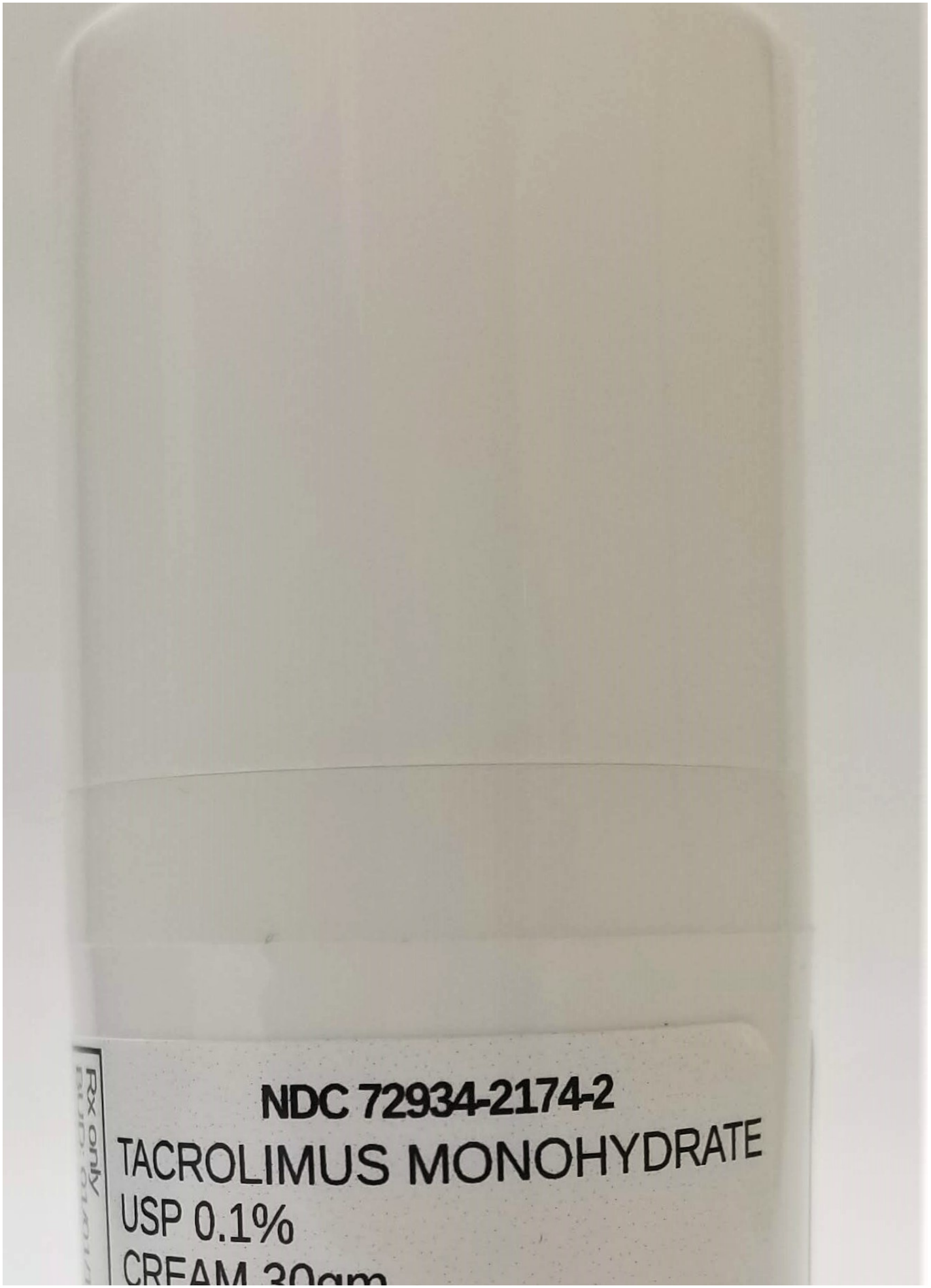
Sincerus Florida, LLC (800) 604-5032
3265 W McNab Rd, Pompano Beach, FL 33069
To report suspected adverse reactions, contact
Sincerus Florida, LLC at (800) 604-5032, or FDA
at www.FDA.gov/MedWatch or (800) FDA-1088.

Office use only. Not for resale.

Active, inactive



NDC 72934-2174-2 / TACROLIMUS USP 0.1%. Cream 30gm


Rx only
NDC 72934-2174-2
TACROLIMUS MONOHYDRATE
USP 0.1%
CREAM 30gm

TACROLIMUS 0.1% IN PSEUDOCATALASE

tacrolimus 0.1% in pseudocatalase cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72934-2174
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

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72934-2174-2	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(72934-2174)

Revised: 4/2019 Sincerus Florida, LLC