

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



...ing FACTROLIMUS cream...
...d be avoided, and application...
...ment with atopic dermatitis...
...ROLIMUS Creams/Ointments...
...ren less than 2 years of age...
...olimus should not be used in...
...immunocompromised adults...
...children.

Directions for use

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



Sincerus Florida, LLC adverse reactions.



CONTAINS TACROLIMUS Cream/Ointment for external use only. For information on the use of TACROLIMUS Cream/Ointment, see the full prescribing information. TACROLIMUS Cream/Ointment 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



TACROLIMUS
USP 0.1%
CREAM



Rx only
BUD: 01/01/1970

Lot: 2111010ABCDEF@1
MFG: 01/01/1970

Active ingredients

Tacrolimus Monohydrate USP 0.1%

Inactive ingredients

Calcium Chloride Fcc Anhydrous 0.146%

Manganese Chloride USP Tetrahydrate 0.208%

Purified Water, USP 3.02%

Sodium Bicarbonate USP 2.29%

Suspendisse Cream 94.236%

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. See full prescribing information for details.

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

Rx only
NDA 019101

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