

**CALCIPOTRIENE 0.005% / CLOBETASOL PROPIONATE 0.05% - calcipotriene 0.005% / clobetasol propionate 0.05% solution**

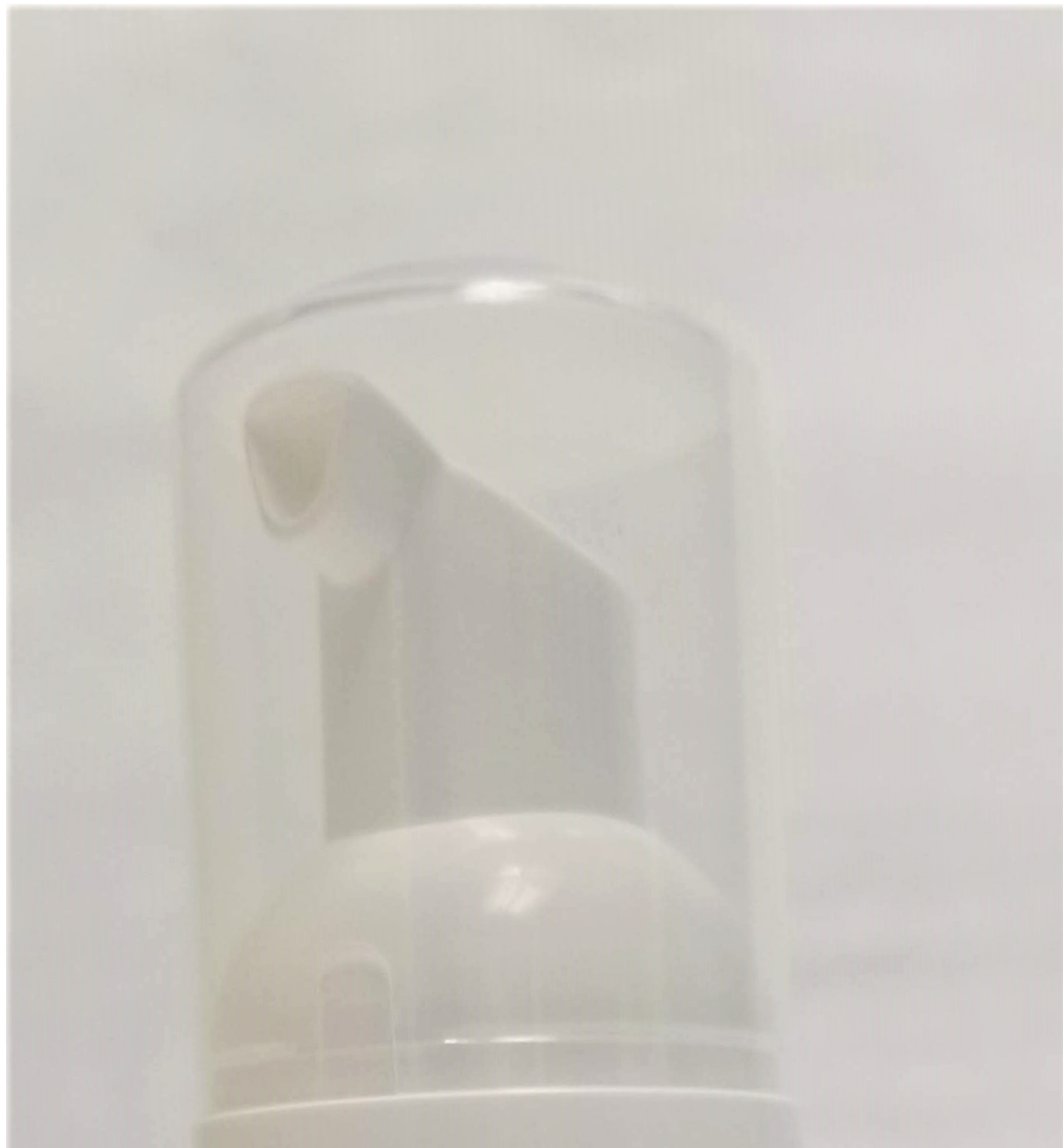
**Sincerus Florida, LLC**

*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](#).*

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**CALCIPOTRIENE 0.005% / CLOBETASOL PROPIONATE 0.05%**

**Directions for use.**



**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](http://www.FDA.gov/MedWatch) or (800) FDA-1088.

Office use only. Not for resale.



OROUS

DATE

FDA



**Sincerus Florida, LLC. Adverse reactions**



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PROUS  
ATE

DA



**Active, inactive**



CALC  
USP  
CLOB  
USP  
SOLU



Rx only  
BUD: 01/01/1970

Lot 091137ABCD EFGH@1  
MFG: 01/01/1970

**Active ingredients**

|                             |        |
|-----------------------------|--------|
| Calcipotriene Anhydrous USP | 0.005% |
| Clobetasol Propionate USP   | 0.05%  |

**Inactive ingredients**

|                            |         |
|----------------------------|---------|
| Preserved Water (parabens) | 20%     |
| Solubilisant Li            | 3%      |
| Suspendisse Foam           | 76.945% |

**NDC 72934- 4029-3 CALCIPOTRIENE USP 0.005% / CLOBETASOL PROPIONATE USP 0.05%. Solution 60 gm**



| RAY        | LOT    |
|------------|--------|
| 0000000000 | 001197 |

The logo for SINCERUS FLORIDA features the word "SINCERUS" in white capital letters on a teal background, and "FLORIDA" in white capital letters on an orange background. The two backgrounds are separated by a white, stylized, wavy line that resembles a ribbon or a path.

This is a compounded drug.  
Made in USA

calcipotriene 0.005% / clobetasol propionate 0.05% solution



| Product Information                                                     |                                          |                                                           |                          |                     |
|-------------------------------------------------------------------------|------------------------------------------|-----------------------------------------------------------|--------------------------|---------------------|
| Product Type                                                            |                                          | HUMAN PRESCRIPTION DRUG                                   | Item Code (Source)       | NDC:72934-4029      |
| Route of Administration                                                 |                                          | TOPICAL                                                   |                          |                     |
|                                                                         |                                          |                                                           |                          |                     |
| Active Ingredient/Active Moiety                                         |                                          |                                                           |                          |                     |
| Ingredient Name                                                         |                                          |                                                           | Basis of Strength        | Strength            |
| CALCIPOTRIENE (UNII: 143NQ3779B) (CALCIPOTRIENE - UNII:143NQ3779B)      |                                          |                                                           | CALCIPOTRIENE            | 0.005 g<br>in 100 g |
| CLOBETASOL PROPIONATE (UNII: 779619577M) (CLOBETASOL - UNII:ADN79D536H) |                                          |                                                           | CLOBETASOL<br>PROPIONATE | 0.05 g in 100 g     |
|                                                                         |                                          |                                                           |                          |                     |
| Packaging                                                               |                                          |                                                           |                          |                     |
| #                                                                       | Item Code                                | Package Description                                       | Marketing Start Date     | Marketing End Date  |
| 1                                                                       | NDC:72934-4029-3                         | 60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/20/2019               |                     |
|                                                                         |                                          |                                                           |                          |                     |
| Marketing Information                                                   |                                          |                                                           |                          |                     |
| Marketing Category                                                      | Application Number or Monograph Citation |                                                           | Marketing Start Date     | Marketing End Date  |
| unapproved drug other                                                   |                                          |                                                           | 05/20/2019               |                     |

**Labeler** - Sincerus Florida, LLC (080105003)

| Establishment         |         |           |                         |
|-----------------------|---------|-----------|-------------------------|
| Name                  | Address | ID/FEI    | Business Operations     |
| Sincerus Florida, LLC |         | 080105003 | manufacture(72934-4029) |