

**DAPSONE 8.5% / NIACINAMIDE 2% / SPIRONOLACTONE 5% - dapsone 8.5% / niacinamide 2% / spironolactone 5% gel**

**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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**DAPSONE 8.5% / NIACINAMIDE 2% / SPIRONOLACTONE 5%**

**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.



**Sincerus Florida, LLC. Adverse reactions**



**Directions for use**

As directed by Physician.

Apply topically. For external use only. W

Store at controlled room temperature (2

Sincerus Florida, LLC (800

3265 W McNab Rd, Pompano Beach

To report suspected adverse reactions

Sincerus Florida, LLC at (800) 604-503

at [www.FDA.gov/MedWatch](http://www.FDA.gov/MedWatch) or (800) F

Office use only. Not for resal



**Active, inactive**



DAPS  
NIAC  
SPIR  
GEL



Rx only  
BUD: 01/01/1970  
Lot 011507 ABCDEFGH@1  
MFG: 01/01/1970

**Active ingredients**

Dapsone USP ..... 8.5%  
Niacinamide USP ..... 2%  
Spironolactone USP ..... 5%

**Inactive ingredients**

Lavender Oil ..... 0.25%  
Propylene Glycol USP ..... 5%  
Suspendisse Gel ..... 79.25%

USP 5%. Gel 30gm



**NDC 72934-1064-2**

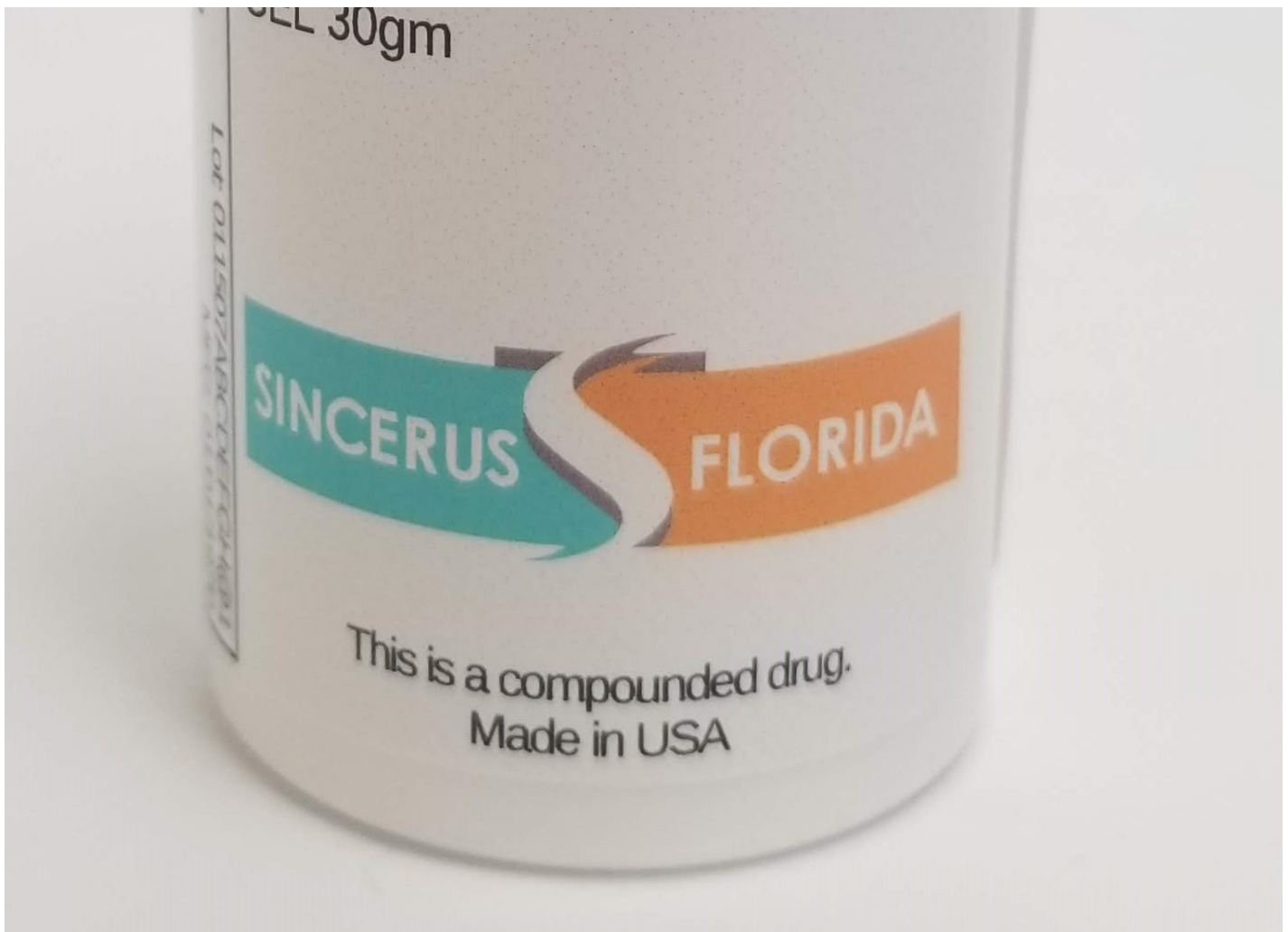
DAPSONE USP 8.5%

NIACINAMIDE USP 2%

SPIRONOLACTONE USP 5%

GEL 30

Rx only  
NDC 72934-1064-2



**DAPSONE 8.5% / NIACINAMIDE 2% / SPIRONOLACTONE 5%**

dapsone 8.5% / niacinamide 2% / spironolactone 5% gel

**Product Information**

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:72934-1064 |
| <b>Route of Administration</b> | TOPICAL                 |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| SPIRONOLACTONE (UNII: 27O7W4T232) (SPIRONOLACTONE - UNII:27O7W4T232) | SPIRONOLACTONE    | 5 g in 100 g   |
| DAPSONE (UNII: 8W5C518302) (DAPSONE - UNII:8W5C518302)               | DAPSONE           | 8.5 g in 100 g |
| NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)       | NIACINAMIDE       | 2 g in 100 g   |

**Product Characteristics**

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

**Packaging**

| # | Item Code        | Package Description                                       | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72934-1064-2 | 30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/10/2019           |                    |

**Marketing Information**

| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other |  | 05/10/2019           |                    |

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

| Name                  | Address | ID/FEI    | Business Operations     |
|-----------------------|---------|-----------|-------------------------|
| Sincerus Florida, LLC |         | 080105003 | manufacture(72934-1064) |

Revised: 5/2019

Sincerus Florida, LLC