**NIACINAMIDE 4% / SPIRONOLACTONE 5% - niacinamide 4% / 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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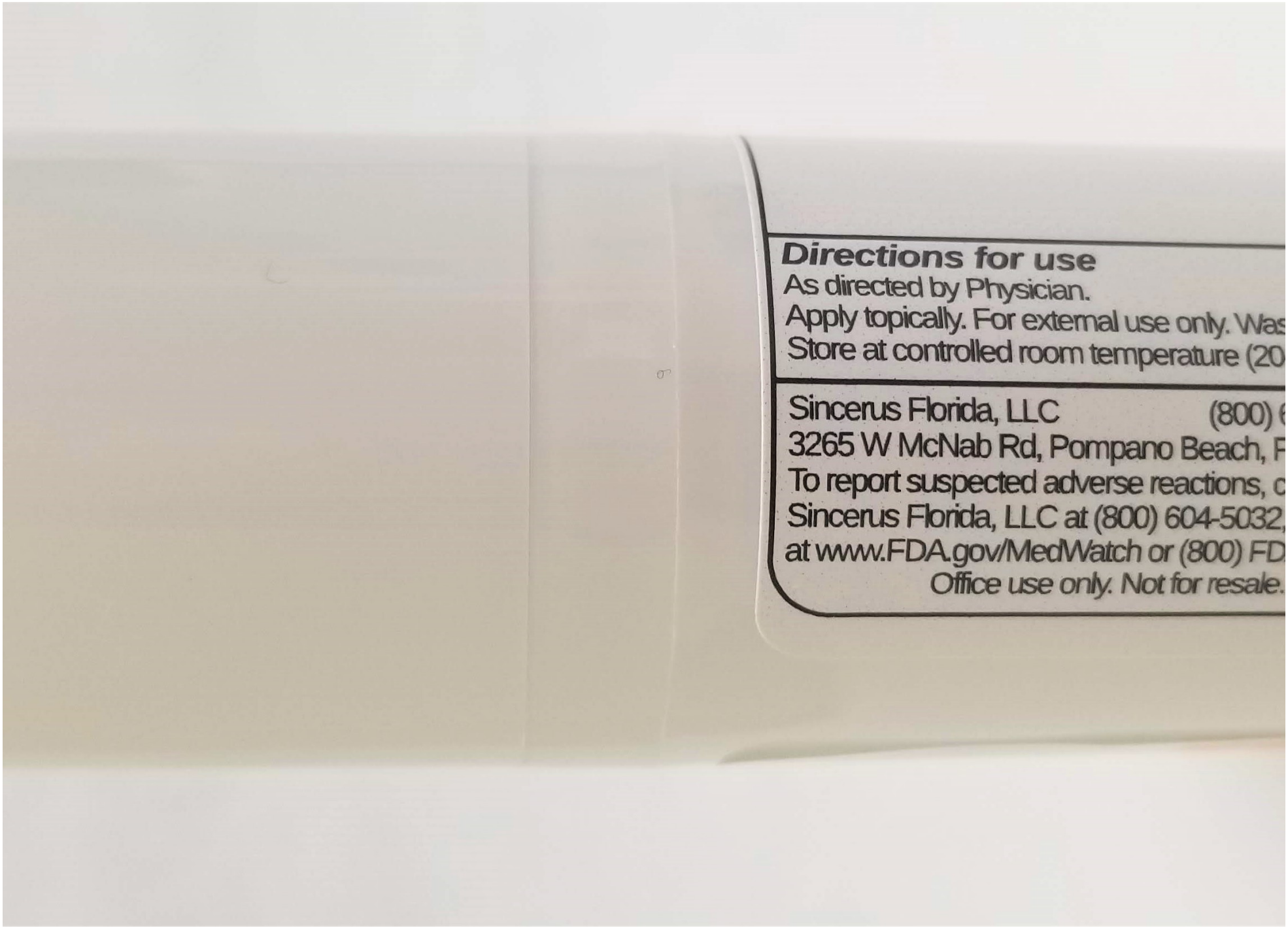
**NIACINAMIDE 4% / SPIRONOLACTONE 5%**

**Directions for use**

**Sincerus Florida, LLC. Adverse reactions**



**Directions for use**
As directed by Physician.
Apply topically. For external use only. Was
Store at controlled room temperature (20

Sincerus Florida, LLC (800) 6
3265 W McNab Rd, Pompano Beach, F
To report suspected adverse reactions, c
Sincerus Florida, LLC at (800) 604-5032,
at www.FDA.gov/MedWatch or (800) FD
*Office use only. Not for resale.*

**Active, inactive**

**NDC 72934-1157-2 NIACINAMIDE USP 4% / SPIRONOLACTONE USP 5%. Gel 30gm.**


Rx only
NDC 72934-1157-2
NIACINAMIDE USP 4%
SPIRONOLACTONE USP 5%


# NIACINAMIDE 4% / SPIRONOLACTONE 5%

niacinamide 4% / spironolactone 5% gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:72934-1157 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **NIACINAMIDE** (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4) | NIACINAMIDE | 4 g in 100 g |
| **SPIRONOLACTONE** (UNII: 27O7W4T232) (SPIRONOLACTONE - UNII:27O7W4T232) | SPIRONOLACTONE | 5 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:72934-1157-2 | 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(72934-1157) |

Revised: 5/2019 Sincerus Florida, LLC