

BENZOYL PEROXIDE 5% / CLINDAMYCIN 1% / NIACINAMIDE 2% / SPIRONOLACTONE 2% / TRETINOIN 0.025% - benzoyl peroxide 5% / clindamycin 1% / niacinamide 2% / spironolactone 2% / tretinoin 0.025% 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](#).

BENZOYL PEROXIDE 5% / CLINDAMYCIN 1% / NIACINAMIDE 2% / SPIRONOLACTONE 2% / TRETINOIN 0.025%

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 or (800) FDA-1088.

Office use only. Not for resale.



Sincerus Florida, Adverse reactions



Directions for use

As directed by Physician.

Apply topically. For external use only.

Store at controlled room temperature.

Sincerus Florida, LLC

3265 W McNab Rd, Pompano Beach, FL 33069

To report suspected adverse reactions, contact

Sincerus Florida, LLC at (800) 604-4444

at www.FDA.gov/MedWatch or (800) 555-0161

Office use only. Not for patient use.



Active, inactive



BB 03 20 05 12 03

Rx only Lot 0115Z1ABCDEF01
BUD: 01/01/1970 MFG: 01/01/1970

Active ingredients

| | |
|---------------------------|--------|
| Benzoyl Peroxide USP | 5% |
| Clindamycin Phosphate USP | 1% |
| Niacinamide USP | 2% |
| Spironolactone USP | 2% |
| Tretinoin USP | 0.025% |

Inactive ingredients

| | |
|-----------------|---------|
| Glycerin USP | 5% |
| Lavender Oil | 0.25% |
| Suspendisse Gel | 84.725% |

**NDC 72934-1015-2. BENZOYL PEROXIDE USP 5%, CLINDAMYCIN PHOSPHATE USP 1%,
NIACINAMIDE USP 4% / SPIRONOLACTONE USP 2% / TRETINOIN USP 0.025%.
Gel30gm.**



Rx only
BUID: 01/01/19

NDC 72934-1015-2

**BENZOYL PEROXIDE USP 5%
CLINDAMYCIN PHOSPHATE
USP 1%**



BENZOYL PEROXIDE 5% / CLINDAMYCIN 1% / NIACINAMIDE 2% / SPIRONOLACTONE 2% / TRETINOIN 0.025%

benzoyl peroxide 5% / clindamycin 1% / niacinamide 2% / spironolactone 2% / tretinoin 0.025% gel

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:72934-1015 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|------------------|
| BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM) | BENZOYL PEROXIDE | 5 g in 100 g |
| CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C) | CLINDAMYCIN PHOSPHATE | 1 g in 100 g |
| TRETINOIN (UNII: 5688UTC01R) (TRETINOIN - UNII:5688UTC01R) | TRETINOIN | 0.025 g in 100 g |

| | | |
|--|----------------|--------------|
| NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4) | NIACINAMIDE | 2 g in 100 g |
| SPIRONOLACTONE (UNII: 27O7W4T232) (SPIRONOLACTONE - UNII:27O7W4T232) | SPIRONOLACTONE | 2 g in 100 g |

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | yellow | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72934-1015-2 | 30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/04/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 05/04/2019 | |

Labeler - Sincerus Florida, LLC (080105003)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|-------------------------|
| Sincerus Florida, LLC | | 080105003 | manufacture(72934-1015) |

Revised: 5/2019

Sincerus Florida, LLC