

**BRIMONIDINE TARTRATE 0.25% / IVERMECTIN 1% / METRONIDAZOLE 1% /  
NIACINAMIDE 4% - brimonidine tartrate 0.25% / ivermectin 1% / metronidazole 1% /  
niacinamide 4% 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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**BRIMONIDINE TARTRATE 0.25% / IVERMECTIN 1% / METRONIDAZOLE 1% /  
NIACINAMIDE 4%**

**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.

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](http://www.FDA.gov/MedWatch) or (800) 555-0161

Office use only. Not for patient use.





**Active, inactive**



BR  
0.25  
ME  
ME  
NI  
GE

Lot 171082ABCD EFGH01

Rx only  
BUD: 01J01/1970

MFG: 01J01/1970

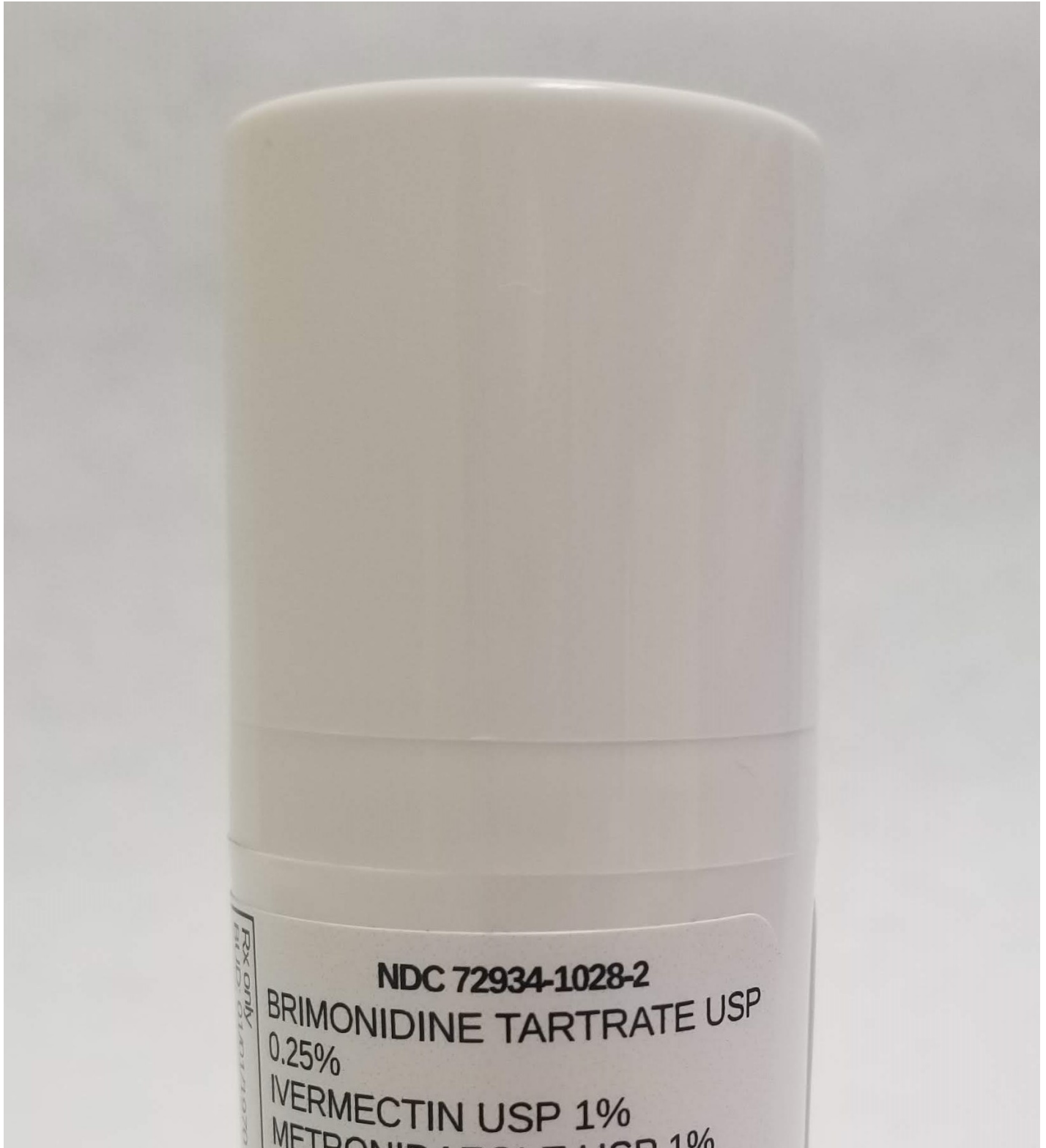
**Active ingredients**

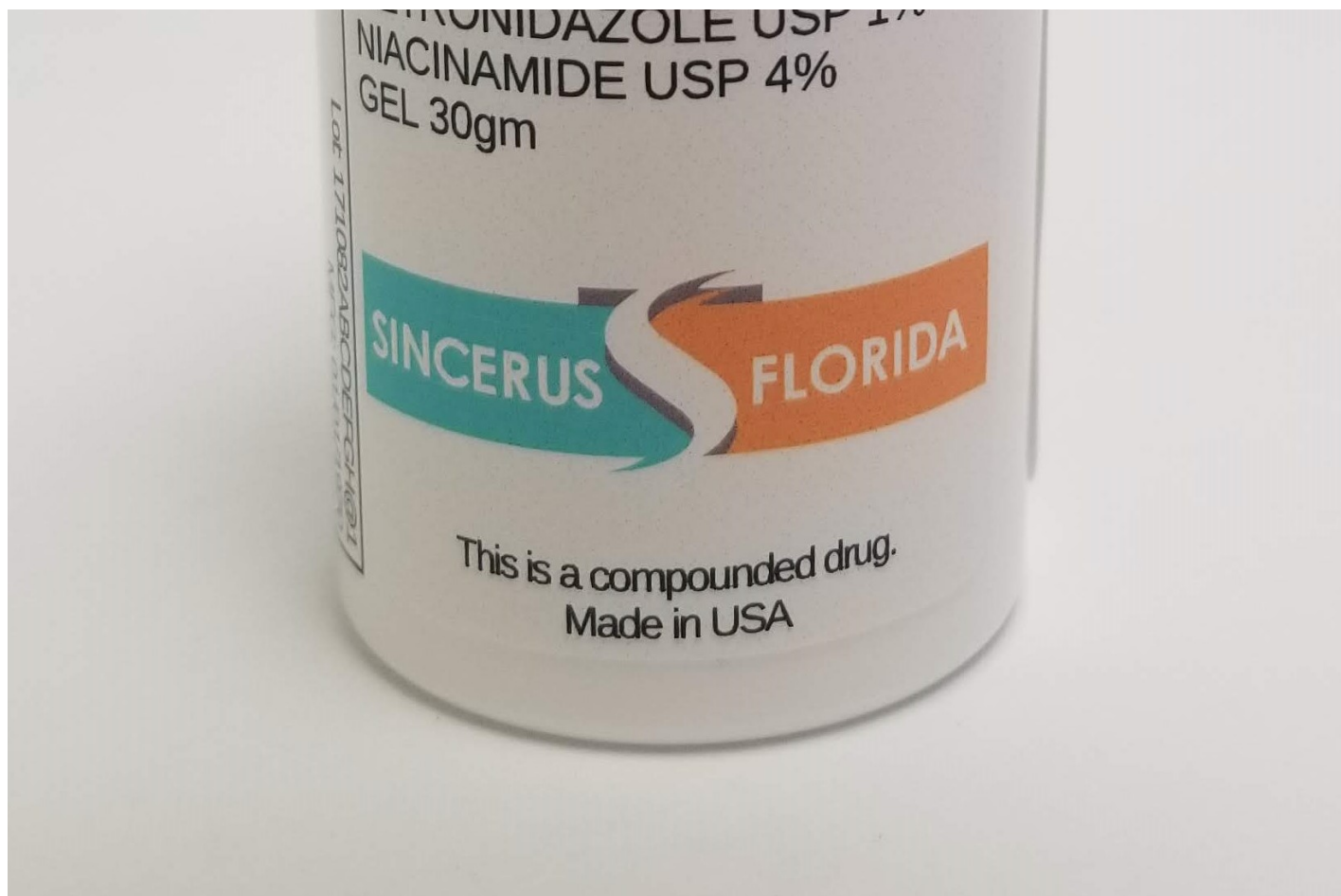
|                          |       |
|--------------------------|-------|
| Brimonidine Tartrate USP | 0.25% |
| Ivermectin USP           | 1%    |
| Metronidazole USP        | 1%    |
| Niacinamide USP          | 4%    |

**Inactive ingredients**

|                               |        |
|-------------------------------|--------|
| Krisgel 100                   | 3%     |
| Potassium Azeloyl Diglycinate | 5%     |
| Suspendisse Gel               | 85.75% |

**NDC 72934- 1028-2 BRIMONIDINE TARTRATE USP 0.25% / IVERMECTIN USP 1% /  
METRONIDAZOLE USP 1% / NIACINAMIDE USP 4%**





**BRIMONIDINE TARTRATE 0.25% / IVERMECTIN 1% / METRONIDAZOLE 1% / NIACINAMIDE 4%**

brimonidine tartrate 0.25% / ivermectin 1% / metronidazole 1% / niacinamide 4% gel

**Product Information**

|                                |                         |                           |                |
|--------------------------------|-------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:72934-1028 |
| <b>Route of Administration</b> | TOPICAL                 |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength    | Strength        |
|--|----------------------|-----------------|
| <b>BRIMONIDINE TARTRATE</b> (UNII: 4S9CL2DY2H) (BRIMONIDINE - UNII:E6GNX3HHTE) | BRIMONIDINE TARTRATE | 0.25 g in 100 g |
| <b>METRONIDAZOLE</b> (UNII: 140QMO216E) (METRONIDAZOLE - UNII:140QMO216E)      | METRONIDAZOLE        | 1 g in 100 g    |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)          | NIACINAMIDE          | 4 g in 100 g    |
| <b>IVERMECTIN</b> (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)            | IVERMECTIN           | 1 g in 100 g    |

**Product Characteristics**

|                 |                        |                     |  |
|-----------------|------------------------|---------------------|--|
| <b>Color</b>    | yellow (OFF WHITE GEL) | <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:72934-1028-2 | 30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/16/2019           |                    |

## Marketing Information

| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other |  | 05/16/2019           |                    |

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

## Establishment

| Name                  | Address | ID/FEI    | Business Operations     |
|-----------------------|---------|-----------|-------------------------|
| Sincerus Florida, LLC |         | 080105003 | manufacture(72934-1028) |

Revised: 5/2019

Sincerus Florida, LLC